**Continuing Review**

Effective on **January 21, 2019**, **Continuing Review will no longer be required** for:

* Most studies that qualify for the expedited review process.
* Studies (regardless of review path) that have **completed subject intervention/interaction** and in which activity is limited to either final **analysis of identifiable data/biospecimens** or involve accessing follow-up clinical data from procedures that subjects undergo as part of clinical care.

Eliminating continuing review for qualifying minimal-risk research reduces administrative burden for both the study team and IRB staff without impact to the human subjects.

**Transition Process**

EXISTING STUDIES

For existing minimal risk studies (expedited) and exemptions that are approved on or before January 20, 2019, the pre-2018 Common Rule will apply. If an existing study is federally funded after January 20, 2019, it will be transitioned to the 2018 Common Rule.

NEW STUDIES

For new expedited studies approved on or after January 21, 2019 (January 22 due to holiday on the 21st), the UC Merced IRB will determine the need for continuing review. Most expedited studies will not require continuing review. Reasons a study might maintain continuing review:

* The projects is regulated by a sponsor that requires continuing review (FDA)
* The project involves additional regulatory oversight, such as COI
* The research will be conducted internationally and/or research with a reliance agreement
* The investigator has had previous serious non-compliance or a pattern of non-compliance

**New Process: 5-Year Administrative Check-In**

In order to close-out studies that are no longer active, all studies (not assigned an annual expiration date) will undergo an administrative check-in at the 5 year mark.

**Researcher Responsibilities**

Although, in most cases, continuing review will not be required, the researchers are still responsible for:

* Submitting modifications for project changes,
* Report Adverse Events; and,
* Terminate the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.

**Exemption Changes**

As of **January 21, 2019** with the implementation of the revised Common Rule, the [**current federally-defined exemption categories for human subjects research (link is external)**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(b)) with:

* Modification to most existing categories
* Expansion in scope to several existing categories
* Addition of new categories
* New exempt determination processes applicable in specific circumstances: Limited IRB review

These changes reflect the recent trends in research oversight to reduce administrative burden on investigators and IRBs for minimal-risk research.

**Category Changes – Overview**

#1 – EDUCATIONAL EXEMPTION

What’s New: Research that involves possible “adverse effects” on student learning of the required education content and/or on the assessment of educators is not eligible for this category.

#2 – SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR

What’s New: Expanded scope to include the collection of sensitive and identifiable data. Exclusions apply:

* Interventions
* Collection of biospecimens
* Linking to additional personally-identifiable data
* Research with children (*except*for educational tests or some public observation)

#3 – BENIGN BEHAVIORAL INTERVENTION (NEW CATEGORY)

What’s New: Permits data collection via an interaction (survey, interview, audio/visual recording, etc.) from adult subjects with prospective agreement. Exclusions apply:

* Research with children
* Deception, unless prior agreement obtained
* Physiological data collection methods (EGG, wearable devices, such as FitBit, blood pressure monitors, etc.)
* Linking to additional personally-identifiable data

#4 – SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS

What’s New: Scope expanded to allow:

* Prospective data review
* Maintenance of identifiers, if all study data is protected health information (PHI)
* Research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities

#5 – PUBLIC BENEFIT/SERVICE PROGRAM RESEARCH (FEDERAL DEMONSTRATION PROJECTS)

What’s New: Project must be published on a federal website.

#6 – TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE

What’s New: Unchanged

#7 – STORAGE/MAINTENANCE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH “BROAD CONSENT” (NEW)

This category will not be implemented at UC Merced.

#8 – USE OF IDENTIFIABLE DATA/BIOSPECIMENS OBATINED WITH “BROAD CONSENT” (NEW)

This category will not be implemented at UC Merced

**New Process**

Limited IRB Review is a type of expedited review process required in the Common Rule. Its purpose is to ensure privacy/confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data (exemptions 2, 3 and 8) **and**, for exemption 7, that "broad consent" was obtained and (if appropriate) documented according to an approved protocol. For exempt studies involving access to PHI (e.g., from medical records), the required Privacy Board review may be integrated with Limited IRB Review by the same assigned reviewer. **UC Merced will not implement category 7 and 8**.

**Transition Process**

EXISTING STUDIES

* Existing exempt studies will not transition to the new categories.
* Existing expedited studies that may fall under a new exempt category will not be transitioned unless agreed upon by the IRB and researchers associated with the study or the study obtains federal funding.

NEW STUDIES

* New studies that qualify for an exemption submitted after January 21, 2019 will utilize the new exemption categories.

**Informed Consent**

Under the revised Common Rule, the **requirements for informed consent** will change, with the addition of:

* "Key information" to be presented at the beginning of the consent form found on our [new templates](https://rci.ucmerced.edu/irb/resources/forms) **if a consent form is over 3 pages.**
* [New consent elements](https://rci.ucmerced.edu/node/25)
* Changes to waiver criteria and documentation
* Broad Consent

The intent of these changes is to facilitate the subjects' understanding of the proposed research and also ensure that they understand how their data and biospecimens may be used.

**Key Information**

The preamble to the Final Rule lists five factors suggested as “key information” that would likely assist a potential subject in understanding the nature of the project and in determining participation.

* A statement that the project is research and participation is voluntary.
* A summary of the research, including: Purpose, duration, list of procedures
* Reasonable, foreseeable risks or discomforts
* Reasonable, expected benefits
* Alternative procedures or course of treatment, if any.

Many SBER studies already employ a brief informed consent document, thus, including the “key information” section would be redundant.

**New Consent Elements**

When your study involves the collection of identifiable private information or identifiable biospecimens the informed consent must include a statement indicating whether:

* identifiers may be removed, and
* de-identified information or biospecimens may or may not be used or shared for future research.

When your study involves use of biospecimens the informed consent should include a statement indicating whether:

* biospecimens may be used for commercial profit, and
* the subjects will share in the profit

When your study involves clinically relevant results the informed consent should include a statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions

When your study involves whole genome sequencing the informed consent should include a statement indicating that the research will or might include whole genome sequencing

**Consent Process Changes**

* A waiver of informed consent for the secondary use of identifiable private information/biospecimens (not covered by Broad Consent) must justify why the use of identifiers is necessary to carry out the research.
* Use of identifiable information/biospecimens to identify potential subjects is allowed without informed consent under certain circumstances
* For federally sponsored clinical trials, a copy of the consent form must be posted to a “publicly available, federal website” (TBD) post-recruitment and no later than 60 days after the last study visit by any subject.

**Broad Consent**

UC Merced will not implement Broad Consent, and therefore the related Exemption Categories 7 & 8) at this time. The tracking requirements are overly burdensome.

**Transition Process**

CONSENT TEMPLATES

2018 Common Rule consent templates are available at our **[Forms website](https://rci.ucmerced.edu/irb/resources/forms)**.

EXISTING STUDIES

Existing studies will not transition to the 2018 Common Rule unless they receive federal funding after January 21, 2019 or if agreed upon by the IRB and researcher. If the study transitions to the 2018 Common Rule, the informed consent forms will need to be revised for studies actively enrolling new subjects.

NEW STUDIES

New studies submitted after January 21, 2019 must utilize an updated informed consent template.