IntegReview IRB policy on Common Rule Changes [effective January 21, 2019].

Key changes	***IntegReview IRB plan for compliance***
Key information to be presented at the beginning of the informed consent	*IntegReview IRB will post an updated informed consent template to the website on January 14th. Study teams should begin using the updated informed consent template as soon as they are available on the website.
New Elements of Informed consent	*The updated informed consent template will include the new elements of informed consent. Study teams should begin using the updated informed consent template as soon as they are available on the website. These new elements are required for Federally-funded projects and strongly recommended for use in other studies.
Waiver of Consent/documentation of consent	The IRBManager application will be appropriately updated to ensure investigators select the correct informed consent category and will reflect the other consent-related regulations (e.g., waiver criteria).
Posting of Informed Consents	For federally-funded clinical trials, a copy of the consent form must be posted to a "publicly available, federal website" post-recruitment and no later than 60 days after the last study visit by any subject.
Broad Consent	IntegReview IRB has no plans to adopt a policy for Broad Consent.
Single IRB Review	IntegReview IRB is now part of the SMART IRB online platform which allows reliance agreements between institutions to be implemented more efficiently using standardized templates. Separate agreement templates are also allowed if institutions prefer to use their own agreements.
Exempt Research	The exempt research categories will be updated on IntegReview's New Study Submission form. No action is required for studies that have previously received exempt determinations. These new categories will apply to all projects regardless of being federally funded or not.
Continuing Review	IntegReview IRB will still require continuing review for all research projects. This will allow IntegReview to monitor participant safety and wellbeing and ensures that Investigators and the studies under our oversight remain in compliance with regulatory and IRB standards. Please note: IntegReview has reduced the fee for the Continuing Review of expedited review projects [minimal risk research].

*New federally funded studies submitted for IRB review on or after January 21, 2019 must utilize an updated informed consent template to ensure compliance with the revised Common Rule. Additionally,

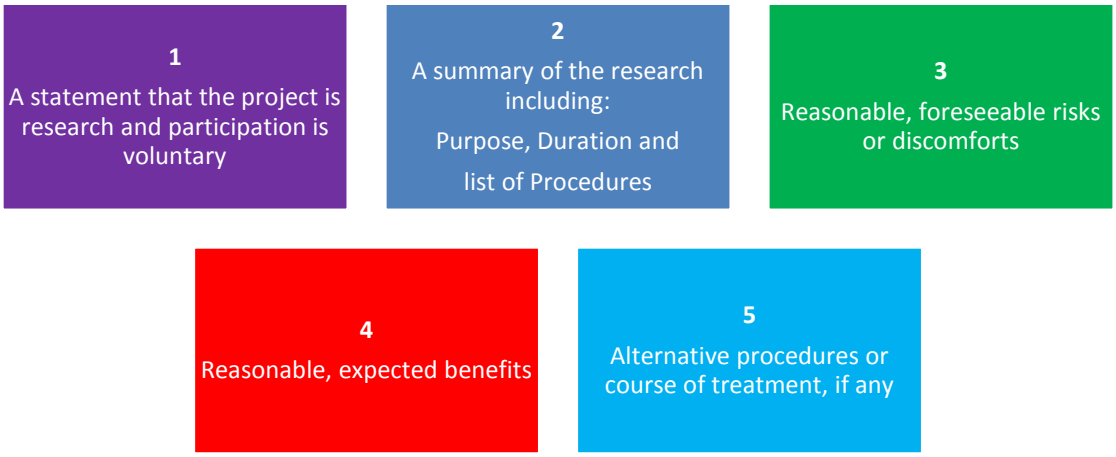
those studies that are ongoing and required to comply with the Common Rule can make necessary updates to their informed consent at that time.

Due to the differing nature of the research and the volume of approved studies, IntegReview IRB will be taking individualized approaches towards transitioning existing studies to comply with the revised Common Rule, including any updates to informed consent documentation. For further information you may contact Melanie Flores, IntegReview's Vice President of Compliance, at mflores@integreview.com.

Please note: for FDA regulated research that is not federally funded these changes noted in the Common Rule do not apply. For additional guidance for FDA regulated studies, please see the guidance document titled "Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations".

Key Information

The preamble to the Final Rule (revised) lists five (5) factors as suggested "key information" that would likely assist a potential participant in understanding the nature of the project and in determining their participation, which include:



How your study team applies the "key information" requirement, and to what level of detail, will depend on the complexity of the research project. Many social/behavioral research projects already employ a brief informed consent document, so including a "key information" section may be redundant. The Final Rule preamble includes some considerations regarding the application of this requirement, but further federal guidance is expected at a later date.

New Elements of Informed Consent

When your project will involve...	Include in the informed consent...
The collection of identifiable private information or identifiable biospecimens	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
Use of biospecimens	A statement indicating whether: • biospecimens may be used for commercial profit, and • the subject will share in that profit
Clinically relevant results	A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions
Whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)	A statement indicating that the research will or might include whole genome sequencing

Waiver of Consent/documentation of consent

- A waiver of informed consent for the secondary use of identifiable private information/biospecimens must justify why the use of identifiers is necessary to carry out the research.
- Use of identifiable information/biospecimens to identify potential subjects (i.e., screening for recruitment purposes) is allowed without informed consent under certain circumstances. A waiver of consent will no longer be needed for these screening activities.

Note: HIPAA requirements still apply - including requesting a HIPAA waiver.

Consent Process Changes

For federally-funded clinical trials, a copy of the consent form must be posted to a "publicly available, federal website" post-recruitment and no later than 60 days after the last study visit by any subject.

The Sponsor/Investigator should develop a plan for ensuring compliance with the new policy.

The Office for Human Research Protections (OHRP) has just identified "two publicly available federal websites that will satisfy the consent form posting requirement" in the revised Common Rule: http://ClinicalTrials.gov and a docket folder on http://Regulations.gov. More places may be identified in the future.

Broad Consent

Under the current regulations, secondary research use of identifiable data/biospecimens is permissible through study-specific consent, by obtaining an IRB waiver of consent, or by removal of identifiers.

In the revised Common Rule, "Broad Consent" is an (optional) alternative consent process for use only for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be-specified research. To utilize "Broad Consent," the study team and/or the unit/biorepository responsible for the storage of the identifiable data/ biospecimens are required to:

- identify the types of research that may be conducted with the data/biospecimens, and
- record and track who has agreed to or refused consent, and
- track the terms of consent to determine whether proposed future secondary research use falls within the scope of the identified types of research

For full details about "Broad Consent" including the requirements (in addition to tracking), limitations, and considerations for use, see SACHRP's *Recommendations for Broad Consent Guidance*.

At this time, IntegReview IRB will not approve the use of Broad Consent; therefore, the IRB will not accept any submission(s) for Exempt Determination Categories 7 and 8.

IntegReview IRB will continue to support research studies seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:

- Study-specific consent and comprehensive IRB review
- IRB waiver of consent (as eligible) and comprehensive IRB review
- Exemption #4

Exemption Category Changes - Overview

Here is an overview of the high-level changes for each exemption category. Further details about each exemption are available in the Common Rule Changes at CFR 46.104.

#1 - EDUCATIONAL EXEMPTION
What's New: A new *ineligibility* criterion will be added to this interaction/intervention exemption for research that involves possible "adverse effects" on student learning of the required education content and/or on the assessment of educators.

#2 - SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR
What's New: The scope will be expanded to include the collection of sensitive and identifiable data. However, the following is not allowed:

- Interventions
- The 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)
A "benign intervention" is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact.
What's New: This new exemption permits data collection via an interaction (e.g., survey, interview, audio/visual recording) from adult subjects with prospective agreement. However, the following is **not allowed**:

- Research with children
- Deception, unless prior agreement obtained
- Physiological data collection methods (e.g., EEG; wearable devices, such as FitBit™; blood pressure monitors)
- Linking to additional personally-identifiable data

The current federal exemption #3 will be eliminated.

#4 - SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/ BIOSPECIMENS)
What's New: The scope of this exemption will be 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: A new *eligibility* criterion for this interaction/intervention exemption will be that the 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)
What's New: This new exemption allows for the storage of data and/or specimens in a repository, with identifiers maintained, that were collected under an approved IRB protocol with Broad Consent for future secondary use research.


IntegReview will not implement Exemption #7 at this time

#8 - USE OF IDENTIFIABLE DATA/BIOSPECIMENS OBTAINED WITH "BROAD CONSENT" (NEW)

What's New: This new exemption allows for secondary research use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with Broad Consent.

IntegReview will not implement Exemption #8 at this time

NEW PROCESSES

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 and 3). 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.

EXISTING STUDIES

- Existing *Exempt* studies **will not be** converted to the new "interaction/intervention" application type. Future amendments will be permitted for **administrative changes only** (i.e., for personnel changes or to record new funding for the project). For changes to the research design you will be required to file a new application (i.e., submit a new study).

- Some existing studies may now qualify for exemption under the 2018 Common Rule. The new exempt status can be determined via an amendment submitted to the IRB or at the time of continuing review.

NEW STUDIES

New studies submitted for an exempt determination **after** January 21, 2019 will utilize the new exempt determination categories and the IRB new submission form. The revised Common Rule will apply to these studies.