# **Revised Common Rule Transition Form: Request for Reclassification to Exempt**

**When to use this form**

Submit this Form if you are requesting a reclassification of your study from Expedited to Exempt following the implementation of the Revised Common Rule, which became effective January 21, 2019. Your study has to meet the requirements for an exempt category as noted below.

Things to note:

* This form should only be used if the current study was approved prior to January 21, 2019.
* This request is only applicable to studies previously approved via the expedited or full board review process that will meet the criteria for exemption as outlined below.
* An online [amendment application](https://research.utexas.edu/irbaccess/action/amendment) must be submitted via IRBaccess to request reclassification.
* A copy of this form along with a copy of the study proposal is required at time of submission of the amendment. Additionally, if the study will qualify for exempt category 3 (criteria outlined below), a copy of the prospective agreement information provided to the participants is required.
* Requests for reclassification will be accepted on a rolling basis and will be reviewed as time permits, which may not be within the 7-10 day amendment review timeframe as these requests will be considered a non-essential study change.
* The IRB staff may contact you if additional information is required for reclassification.

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| **Study Details:** |
| IRB Study Number:  | Click or tap here to enter text. |

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| **Study Elements:** |
| Select | The research is FDA regulated. |
| Select | Prisoners are purposefully targeted for this study. |
| Select | Minors are eligible to participate. |
| Select | Identifiers are collected for this research. |
| Select | The research introduces materials or topics participants may reasonably find offensive or embarrassing. |
| Select | Disclosure of subject’s responses will not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. |
|  | If no, describe why the data collected will not affect social standing or personal liability:Click or tap here to enter text. |
| Select | Subjects are deceived as to the nature of the research. |
|  | Select | If yes, subjects are prospectively informed that they will be deceived. *Upload information form with application to IRB access.* |

**Exempt Category Reclassification:**

Choose **one** of the following exempt categories that best fits your research study and provide protocol-specific justification as to why your study falls under or meets the requirements for the identified exempt category.

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| **Exempt Category 1** |
|[ ]  Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |
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| **Exempt Category 2** |
|[ ]  Research that **only includes** interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: 1. Data has no identifiers or linked code;
2. If identifiers or code, any disclosure of the research data could not possibly be harmful to subjects; OR
3. If data are identified or coded, the IRB conducts a limited review to determine privacy & confidentiality protections are adequate.

Note: * Research cannot include minors if the researcher will interact with participants.
* Research cannot include intervention.
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| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |
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| **Exempt Category 3** |
|[ ]  Research involving benign behavioral interventions\* in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection if at least one of the following criteria is met: 1. Data has no identifiers or linked code;
2. If identifiers or code, any disclosure of the research data could not possibly be harmful to subjects; OR
3. If data are identified or coded, the IRB conducts a limited review to determine privacy & confidentiality protections are adequate.

Note: * Research cannot include minors.
* The research cannot include data collection that requires sensors (*e.g.*, EEG, EMG, MRI)
* Deception is allowed if participants prospectively agree.

*\*For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include playing an online game, solving puzzles under various noise conditions, deciding how to divide a nominal amount of received cash between themselves and others, etc.* |
| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |
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| **Exempt Category 4** |
|[ ]  Secondary research uses of identifiable private information or identifiable biospecimens if at least one of the following criteria is met: 1. The data or specimens are publicly available;
2. Information is recorded without identifiers or linked code AND the investigator does not contact the subjects nor re-identify subjects;
3. The secondary use research is covered by a HIPAA waiver of authorization or is being done for healthcare operations or public health activities;
4. The research is conducted by, or on behalf of, a Federal department or agency using government generated or government-collected information…

Note: Data no longer has to be existing at started of the study; data may be prospectively collected.  |
| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |
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| **Exempt Category 5** |
|[ ]  Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.Note: Must be published on publicly available Federal website prior to beginning research. |
| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |
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| **Exempt Category 6** |
|[ ]  Taste and food quality evaluation and consumer acceptance studiesNote: Wholesome foods without additives are consumed or additives are in amounts approved by the FDA and USDA. |
| Briefly describe the research activities involved in this project and provide an explanation as to why the research falls under this exempt category.Click or tap here to enter text. |