



Cornell IRB Policies & Procedures Effective January 21, 2019

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1. Introduction

On January 19, 2017, the U.S. Department of Health and Human Services (“HHS”) issued final revisions to the Federal Policy for the Protection of Human Subjects, 45 CFR 46 ([the “New Common Rule” or “New Rule”](#)). These are the first significant changes to human subject regulations since 1991 (the “Old Rule”). While some revisions reduce burdens on researchers and institutions, others involve new requirements. Following a previous delay announced in January 2018, on June 18, 2018, HHS informed researchers of an additional delay in the general compliance date of the New Rule, until January 21, 2019¹ (the “Effective Date”). The Cornell IRB has chosen to take advantage of [flexibility that HHS has granted](#), which allows institutions to implement three burden-reducing provisions of the New Common Rule early. Thus, some of the provisions of the New Common Rule went in effect at Cornell on July 19, 2018.

This document describes key changes introduced by the New Common Rule and how they impact protocols that received IRB approval or exemption before the Effective Date (“Pre-existing Studies”), as well as new studies first approved or exempted after the Effective Date. All researchers should familiarize themselves with the text of the [New Rule](#) and this guidance document, as they design future studies and decipher how the new regulations affect their research².

¹ A new requirement to use a single IRB for certain multi-site studies takes effect on January 20, 2020.

² While the Common Rule only applies to federally conducted or federally sponsored research, as an institution Cornell chooses to apply the regulations to all research conducted by its faculty, staff and students, regardless of funding status.



2. Key Provisions of the New Common Rule

- a) **Changes to Exemption Categories & Review Procedures:** More research projects will qualify for exemption under the New Rule, which adds to and modifies the existing categories, including: broadening previous exemption Category 2 to include use of identifiable, sensitive information if the IRB conducts a special “limited IRB review” and the study meets certain criteria; expanding Category 4 to allow for secondary use of data that is not “on the shelf” at the time of exemption; explicitly permitting exemption of “benign behavioral interventions” (such as playing an online game) and storage and secondary use of identifiable private information and identifiable biospecimens where “broad consent” was obtained. For more information, see Section 3(a), below.
- b) **Elimination of Continuing Review (Renewal) Requirement for Most Studies:** With few exceptions, the annual renewal requirement has been eliminated for expedited review studies and for full board research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data as part of clinical care. Amendments will still need to be filed with the IRB before making changes to approved protocols. For more information, see Section 3(b), below.
- c) **Changes to Informed Consent:** Additional elements have been added to the basic requirements for informed consent, along with a general requirement to begin informed consent with a concise presentation of key information most likely to assist a prospective subject in understanding why they might or might not want to participate. In addition, for clinical trials that are federally-funded, there is a new requirement to post a copy of a consent document after the study is closed to recruitment but within 60 days of the end of data collection. For more information, see Sections 3(c) and (e), below.
- d) **Clinical Trials:** The New Rule expands the concept of “clinical trial”, defining it as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” Researchers with federally-funded clinical trials are responsible for complying with additional requirements. For more information, see Sections 3(c) and 3(e), below.
- e) **New Single IRB (“sIRB”) Requirement:** An sIRB is the IRB of record, selected on a study-by-study basis, which provides the ethical review and related administrative coordination for all sites participating in a multi-site study. Beginning in 2020, the New Common Rule will require use of an sIRB when domestic institutions are engaged in cooperative research. For NIH-funded studies only, a version of the sIRB requirement already applies. For more information, see Section 3(f), below.
- f) **Revised Definitions:** The New Rule includes some new and revised definitions, including narrowing the definition of Human Subjects Research by specifying that certain activities are now no longer included, such as certain scholarly and journalistic activities (such as oral history), public health surveillance and criminal justice and intelligence activities. For more information, see Section 5, below.



3. Detailed description of Changes Affecting Cornell Researchers

a. Changes to Exemption Categories and Review Procedures

As before, under the New Rule some research activities will meet the definition of human participant research but will not require, as a regulatory matter, review and oversight by the Institutional Review Board. The Cornell IRB will still require PIs to submit such studies for an administrative review and formal determination of exemption before they commence research with human participants. Researchers may not self-determine that their work is exempt. The new, single application form available on the website should be used by researchers seeking exemption, or any other level of IRB review.

Revised Exemption Categories

The New Rule introduces major changes to the exemption categories, with all but one category being revised, new categories added, and two new processes introduced: Limited IRB Review and Broad Consent.³ The exemption categories, as they appear in the New Rule, are described below:

Category 1: Research in Established or Commonly Accepted Educational Settings *Restriction added*

This category has been amended to include a requirement that the research is not likely to have adverse impacts on either students learning required educational content, or assessment of educators who provide instruction. As before, it may only be used for studies on normal educational practices.

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior *Broadened*

The New Rule allows for exemption as long as one of three criteria is met:

- Information obtained is not identifiable; or
- Disclosure outside of the research would not put subjects at risk of harm; or
- Information obtained can be identifiable and potentially put participants at risk, but the IRB has done a Limited IRB Review to ensure adequate provisions for privacy and confidentiality

If none of these criteria is met, the research must be reviewed as an expedited protocol. This category has been revised to include visual or auditory recording as research methods. As under the Old Rule, surveys or other permitted research methods cannot be combined or paired with non-exempt methods such as collection of biospecimens, as those additional activities would disqualify the research from this category. When research includes children, Category 2 still cannot be used as the basis of exemption, if the research involves surveys, interviews, or the investigator participating in the activities being observed (observation of public behavior without intervention is permitted).

³ In addition to new exemption categories and changes to existing categories, the New Rule allows all exemption categories to be used for research with prisoners, provided that the research involves a broader subject population and only incidentally includes prisoners (i.e., the research is not seeking to examine prisoners as a subpopulation).



Category 3: Benign Behavioral Interventions with Adult Subjects *New Category*

This is a new category⁴ for benign behavioral research with adults, which must be “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.” An example provided is having subjects solve puzzles under various noise conditions.

Exemption is permitted if:

- the data are recorded in such a way that the identity of the subjects cannot be readily ascertained either directly or indirectly; or
- if a disclosure of the responses outside the research setting would not reasonably place the subjects at risk of harm; or
- if the subjects’ identities can readily be ascertained and disclosure of responses may harm subjects, but the IRB conducts a “Limited Review” and determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

No deception is permitted, unless the subject is told during the consenting process that they will be unaware of or misled about the nature or purposes of the research. Debriefing is encouraged. The type or manner of information collected is important: verbal or written responses (as in surveys/interviews), data entry, observation of the subject (including audiovisual recording) are all permitted. Data collection via physical procedures, including physical sensors (e.g. blood pressure monitors, EEG, FitBits) or minimally invasive procedures (blood draw or saliva collection) is not allowed under this exemption category, and would be reviewed as an expedited protocol.

Category 4: Secondary Research for Which Consent is not Required *Broadened*

Revised in the New Rule, this exemption covers secondary research uses of identifiable private information or identifiable biospecimens. Informed consent is not needed if certain criteria are met. The category has been broadened so that data no longer need to be existing (“on the shelf”) at the time of exemption.

Category 5: Research & Demonstration Projects Conducted or Supported by a Federal Department or Agency *Broadened*

This category now supports exemption of research supported by (not just conducted by) a federal agency.

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies *Unchanged*

This is the only exemption category that is unchanged under the New Rule.

Category 7: Storage or Maintenance under Broad Consent *New Category*

This new category provides exemption for storage and maintenance of identifiable biospecimens

⁴ The Category 3 exemption in the Old Rule has been eliminated.



and identifiable private information, prior to secondary analysis. These activities may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.

Category 8: Secondary Research use under Broad Consent *New Category*

This is a new exemption category for secondary analysis of existing private identifiable data or identifiable biospecimens, provided that broad consent was given and the documentation of consent was obtained or properly waived. A Limited IRB Review is needed, to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and that the proposed secondary use is within the scope of the consent that was given by the research subjects. For this exemption to apply, the researcher may not plan to return individual research results to subjects.

What is a “Limited IRB Review”?

Another significant change to the exemption landscape is a new level of IRB oversight used when making *some* Category 2 and 3 exemption determinations, and for all Category 7 and 8 exemptions. If the IRB is to exempt these studies, a special, narrowly-focused review of certain aspects of the protocol must occur-- a so-called “Limited IRB Review”. The issue that the IRB is examining in a Limited Review varies according to which exemption category is being sought. For specific information, broken down by exemption category, see Appendix A.

Until HHS releases expected guidance on conducting Limited IRB Reviews, the Cornell IRB will use a checklist for conducting the Limited Review needed to exempt studies under categories 2 and 3: determining whether there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The goal of this review is not to impose a different or stricter standard than the one applied to studies that have traditionally received expedited review under the Old Rule, but to formalize and document that standard. See Appendix B for the checklist and information about how the IRB will apply these criteria.

What is “Broad Consent”?

The concept of “Broad Consent” introduced by the New Rule is the process of seeking prospective consent to participate in future, unspecified research. Broad consent must have been obtained in order for storage and secondary research use of identifiable private information or biospecimens to be eligible for exemption under Categories 7 and 8. Under the Old Rule, secondary research use of identifiable data or biospecimens required study-specific consent, an IRB waiver of consent, or the removal of identifiers, once collected. Broad consent is intended to give flexibility to researchers who want to store, maintain or use, for secondary research purposes, identifiable private information or identifiable biospecimens in future, unspecified research, to which the participants have not explicitly given their consent.

To utilize "Broad Consent," the study team and/or the biorepository responsible for the storage of the

data or biospecimens is required to identify the types of research that may be conducted with the data or biospecimens, record and track participants that have agreed or refused their consent, and to track the terms of the consent documents, to determine whether proposed future secondary research use falls within the scope of the consent that was granted. To issue an exemption under new Categories 7 or 8, an IRB must conduct a special Limited Review to determine whether the proposed broad consent is adequate.

Given the lack of guidance from the Office for Human Research Protections (OHRP), the complexity and burden of tracking individuals who do not provide consent and excluding their data from all future research, and because some of the added requirements for broad consent will be extremely challenging to obtain, **broad consent is unlikely to be effectively used at this time by Cornell researchers.** For information on using specimens or information obtained and/or stored under broad consent by outside researchers and facilities, please contact the IRB.

b. Elimination of Continuing Review Requirement for Most Studies

Under the New Rule, the annual renewal requirement is eliminated for all expedited review studies and for full board research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data as part of clinical care.

As permitted by the June 2018 HHS rule-making, the Cornell IRB elected to implement this provision of the New Rule early, beginning on July 19, 2018. As a result, all new expedited review studies approved on or after July 19, 2018 by the Cornell IRB do not have an expiration date listed in the approval letter, and no continuing review is required for these studies.

Similarly, for expedited review protocols that were approved prior to July 19, 2018, Cornell IRB staff will contact Principal Investigators and Faculty Advisors prior to the current scheduled expiration date of each protocol to remind them of the change to the policy and provide an updated approval letter and stamped consent documentation reflecting that there is no formal expiration date. If any changes must be made to a protocol to comply with New Rule requirements, a member of the IRB staff will contact the affected researchers during the first year in which the New Rule is effective. See Section 4, below, for additional information.

Principal Investigators and any Faculty Advisors for expedited review studies will receive an annual courtesy email for each study with a reminder that: an amendment request must be submitted and approved before making changes to the study; unexpected events must be promptly reported to the IRB; and protocols should be formally closed by the investigator upon the completion of the study. While no action will be required in response to the reminder, the IRB recommends that you take the opportunity to ensure that current study personnel, documents and procedures are accurately reflected in your approved protocol.

c. Changes to Informed Consent

Researchers are encouraged to consult the Cornell IRB consent templates, which have been revised to satisfy the standards set forth in the New Rule. The Cornell consent templates that were in use prior to the Effective Date already reflected most of the new principles and elements required by the New Rule. As a result, the approved consent documents for most Pre-existing Studies will not need to be revised to comply with the New

Rule.

Additional Consent Elements

For certain types of research, the New Rule adds new elements to the list of information that must be communicated during the informed consent process (§ 116(c)(7), (8) & (9)):

For research that involves	Informed consent now must now indicate:
Collection of identifiable private information or identifiable biospecimens	Whether de-identified information or biospecimens may or may not be used or shared for future research
Use of biospecimens	Whether biospecimens may be used for commercial profit, and if the subject will share in that profit
Clinically relevant results	Whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions
Whole genome sequencing (sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)	That the research will or might include whole genome sequencing

Concise Statement

In addition to new required information, consent documents under the New Rule must begin with a concise and focused presentation of key information most likely to assist a prospective subject in understanding why they might or might not want to participate in the research-- a summary of study activities, risks, and benefits, presented to research participants on the first page, and organized and presented in a way that facilitates comprehension. (46.116(a)(5)(i)).⁵

Given their simplicity and brevity, the 1-3 page consent forms and scripts typically used in social and behavioral research, and based on Cornell IRB-approved templates, will satisfy the new requirement. On a case-by-case basis, the IRB may determine that changes are needed. If so, IRB staff will work with the PI to revise the consent. Participants in ongoing studies will not need to be re-consented.

d. [Paths to IRB Exemption or Approval of Studies Involving Secondary Data](#)

The New Rule introduces both new flexibility and new restrictions to research with secondary data and biospecimens. Two new exemption categories are added for storage and use of data containing identifiers. In addition, existing Exemption Category 4 for secondary data has been expanded. The following chart summarizes different paths to IRB approval or exemption for research use of secondary data, with and without identifiers, under the New Rule.

⁵ Currently, there is no federal guidance defining these terms. Guidance from OHRP is expected.

Description	Consent	IRB Review Type & Requirements	Notes
Secondary use of non-identifiable biospecimens or identifiable information that is not private	N/A	None - Not regulated under New Common Rule	Do not submit an IRB application for this work
Secondary use of identifiable bio-specimens or identifiable private information (together, “Identifiable Data”)	No specific consent given	Category 4 exemption can be granted if: <ul style="list-style-type: none"> • PI not involved in primary collection of the Identifiable Data; • PI and provider of the Identifiable Data will not co-author the study; • Identifiable Data not collected in an earlier study involving a member of the research team; and • Identifiable Data are publically available; or identifiers are not recorded by researcher; or HIPAA applies⁶ 	Under the New Rule, Identifiable Data no longer needs to be “on the shelf” when exemption is sought (collection can occur simultaneous with its use under Cat. 4 by an unaffiliated researcher)
Storage of identifiable private information or identifiable biospecimens	Researcher who collected data/specimens obtained broad consent	A category 7 exemption can be granted, if: <ul style="list-style-type: none"> • The Identifiable Data were collected for another purpose • Broad Consent was obtained • IRB conducts limited review for broad consent & privacy/confidentiality of data 	This path is unlikely for Cornell researchers
Research use of identifiable private information or identifiable biospecimens	Researcher who collected data/specimens obtained broad consent	A Category 8 exemption can be granted, if: <ul style="list-style-type: none"> • The Identifiable Data were collected for another purpose • Broad Consent was obtained • IRB conducts limited review for broad consent, privacy & confidentiality of data 	Under Old Rule, this was given Cat 5 expedited review. Likely application at Cornell: Cornell PI using Identifiable Data stored in a biobank
Research involving data or specimens that were or will be collected solely for non-research purposes (e.g., medical treatment, diagnosis)	None	Expedited Category 5 (unchanged in New Rule) remains a path to IRB review and approval of research involving secondary use of biospecimens or data, when no exemption category applies	

⁶ Researchers wishing to use HIPAA-protected data should consult the IRB for specific guidance.

e. “Clinical Trials” -- Expanded definition and requirements

“Clinical trial” is defined in Section 102(b) of the New Rule as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” This is identical to the [NIH definition](#), which that agency has interpreted quite broadly. Case studies issued by NOH describe certain fundamental health-related research previously assumed to be outside of the definition. For federally-funded research that meets the Common Rule definition of Clinical Trial, PIs have one or more new compliance obligations, depending on the exact funding source.

To facilitate compliance with these additional requirements for clinical trials, approval letters will specify that a project meets the definition of a “clinical trial” when the IRB determines that this is the case, and summarize requirements that may apply as a result. If your study is a clinical trial you as the researcher are ultimately responsible for ensuring compliance with the obligations summarized here:

Any federal funding: For clinical trials supported by any type of federal funding (NIH, NSF, DOD, etc.), the PI is required to comply with the consent posting requirement described below. In addition, the IRB recommends that federally-funded researchers voluntarily comply with obligations described below that are mandatory only for NIH-funded researchers conducting a clinical trial:

- Consent form posting: The PI must post a copy of an IRB-approved consent form used for enrollment purposes to [ClinicalTrials.gov](#) after the study is closed to recruitment, but not later than 60 days after the last study visit by any subject. Please note that the IRB office will not be able to remind PIs to fulfill this obligation in a timely manner.

NIH funding: If you are a PI who has or is seeking NIH funding for a clinical trial, you are responsible for meeting the following additional compliance obligations:

- Apply for the correct FOA: Certain NIH Funding Opportunity Announcements (FOAs) are applicable only to CTs or non-CTs. Applying for the wrong FOA may make your submission ineligible for funding.
- Registration and reporting on [Clinicaltrials.gov](#): Clinical trials in competing applications and contract proposals submitted on or after January 18, 2017 must register, submit updates throughout the project, and post results information on [Clinicaltrials.gov](#). Compliance with this requirement is expected to require a significant dedication of time and effort throughout the study. IRB approval will not be granted without the NCT number indicating that the initial registration has been completed. The IRB is available to provide assistance if requested, but researchers are primarily responsible for complying with these obligations
- Training in Good Clinical Practices (GCP): Starting January 1, 2017, those involved in the design, conduct, oversight, or management of a NIH clinical trial must be trained in GCP. As a condition of protocol approval, the Cornell IRB will require evidence that all study personnel listed on the protocol have completed GCP training within the last 3 years. NIH does not specify any particular GCP course. Cornell researchers may complete GCP training online through CITI. Note that this training is in addition to basic IRB training required by the IRB.
- Consent form posting: This requirement is described above.

All other projects: Regardless of the funding status or source for your human subjects work, the Cornell IRB strongly recommends that you choose to follow the compliance practices required by NIH as a best practice.

Publication in certain journals could be jeopardized if researchers fail to comply with these best practices.

f. Requirement for Single IRB (sIRB)

The New Common Rule requires, with very few exceptions, that federally funded studies use a single IRB (sIRB) for review and approval of cooperative studies (projects that involve more than one institution) conducted in the United States. Unlike the other provisions in the New Rule, this requirement does not take effect until January 20, 2020. Once further guidance is issued by HHS, the Cornell IRB will make additional information available to the research community.

While the New Rule's sIRB requirement will not take effect immediately, a similar requirement has applied to NIH-funded studies since January 25, 2018. For NIH-funded studies, all multi-site projects with non-exempt human participant research (clinical and non-clinical) where the same research protocol is conducted at more than one domestic sites are required to use an sIRB. The sIRB serves as the institution of record and assumes responsibility for all human participant research compliance. Applicants are required to include an sIRB Plan in their NIH proposal, identifying which IRB has agreed to serve in this role. sIRB costs will be permitted as direct charges under specific circumstances. If selected for award, all participating sites will be required to execute an Authorization Agreement signed by authorized officials for each participating institution. The sIRB requirement for NIH studies will be incorporated into the Notice of Award (NOA) as a term and condition.

The Cornell IRB is not equipped to serve as the sIRB, but will comply with the requirements for a participating IRB when another institution serves as the IRB of record. Researchers should speak with the Cornell IRB office prior to submitting a NIH proposal for a multi-site project. The IRB staff will assist PIs with identifying a suitable partner to act as the sIRB, including other institutions involved in the project or a commercial sIRB provider that has contracted with Cornell.

4. Procedures for Pre-existing Studies

Applicable Policies & Procedures during 2019

Changes mandated by the New Rule impact the majority of the Cornell IRB's existing policies and SOPs. The IRB intends to formally revise all affected policies and SOPs in 2019. In the interim, if any information in this document is inconsistent with information in a previously-issued IRB guidance or policy statement, the statement in this document shall apply.

Which version of the Common Rule applies to my study?

The New Rule applies automatically to all studies approved or exempted by the IRB on or after January 21, 2019. Cornell has chosen to also apply the New Rule to studies that were approved or exempted prior to the Effective Date. For these studies, in the event that changes must be made to study documents or procedures, or if the protocol itself must be reclassified (for example, from expedited under the Old Rule to exempt under the New), the IRB will identify the change to be made and inform the PI.

Definitions

The New Common Rule provides new and revised definitions of several key terms, including: “clinical trial,” “human subject,” “intervention,” “private information,” “identifiable private information,” “identifiable biospecimen,” “minimal risk,” “research,” and “written or in writing”. (§102).

- **Clinical Trial:** The final rule added the definition of “clinical trial,” which was not defined in the previous version of the Common Rule. A clinical trial is “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” (§102(b)).
- **Human Subject:** The New Rule expands the definition of “human subject” to cover the collection of biospecimens. The new definition includes “a living individual about whom an investigator, whether professional or student conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- **Benign Behavioral Intervention:** To be considered a “benign behavioral intervention,” for purposes of the new exemption category 3, interventions conducted in research with human beings must meet all of the following criteria. The intervention must be:
 - brief in duration;
 - harmless;
 - painless;
 - not physically invasive; and
 - unlikely to have significant adverse lasting impact on the participants.

In addition, if the research involves deception, the researcher must alert potential participants in advance to this possibility in the consent documents, and participants must prospectively authorize the deception in their agreement to participate. Research involving children is ineligible for this category of exemption.

- **Activities deemed not to be research:** The final rule amended the definition of “research” to include four new activities that are deemed to not be “research”: (1) scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship); (2) public health surveillance activities; (3) collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes; and (4) certain activities in support of intelligence, homeland, security, defense, or other national security missions. (§102(l)).

5. Selected References

- Federal Policy for the Protection of Human Subjects, Text of New Rule: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>
- Secretary’s Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachments: Attachment B, Recommendations <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html>

Appendix A

Limited IRB Review: Determination to be made under each exemption category

Exemption category	Description	Required limited review determination
2 (expanded)	Surveys, interviews, observation of public behavior, education tests. Limited review needed if PI is <i>recording identifiable information</i> and that information is <i>risky</i> .	Adequate provisions to protect subjects' privacy and maintain confidentiality of data
3 (new)	Benign behavioral interventions with adults. Limited review needed if PI is <i>recording identifiable information</i> and that information is <i>risky</i> .	Adequate provisions to protect subjects' privacy and maintain confidentiality of data
7 (new) ⁷	<i>Storage</i> of identifiable information or bio-specimens for possible secondary research, where info/specimens was obtained using broad consent	Confirm broad consent was properly obtained and documented and, if a change is made to storage, there are adequate provisions to protect subjects' privacy and maintain confidentiality of data
8 (new)	<i>Secondary research use</i> of identifiable information or biospecimens that were obtained using broad consent	There are adequate provisions to protect subjects' privacy and maintain confidentiality of data; the proposed use is within the scope allowed under the broad consent

⁷ As described more fully in Section 3(c), above, because exemption categories 7 & 8 require that broad consent be obtained, we do not expect that these categories of exemption will be used by our researchers.

Appendix B

If the IRB member reviewing an applicable protocol answers “yes” (or “N/A”) to all of the questions below, then the Limited IRB Review standard for ensuring privacy and confidentiality is deemed satisfied:

Privacy of subjects

Collection of direct identifiers is justified & is minimized to the extent possible	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Risk of re-identification is minimized: appropriate plans for maintaining data (ex: identifiers stored separately from responses)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Recruitment & study procedures are conducted privately (i.e., do not ask screening questions in a public place, where others can overhear)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Any information shared outside the research team is de-identified or aggregated	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Consent appropriately informs participants how their data will be shared	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Confidentiality of data

For web-based data collection: approved programs are used (i.e. recruitment via MTurk, but data collection via Qualtrics) to minimize risk of confidentiality breach	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Access to identifiable data is controlled: If transmitting/storing data online, use encryption or upload to secure server (use Cornell Box; no email or unapproved cloud storage)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Passwords/access to identifiers is granted to a small number of people	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Data collected on a laptop or mobile device is securely stored and transmitted (encrypt data or device, move identifiable data off of device ASAP)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Hard-copy study materials are secure (ex: locked office, cabinet, safe)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
When data is no longer necessary, it will be destroyed	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

If the reviewer is unsure of the answer to any checklist item, or if the answer is “no” based on the information provided in the application, the staff member will seek clarification from the PI or suggest alternative procedures that would satisfy the Limited IRB Review standard. Following this discussion, if the Limited Review Standard is still not met, then the study must go through the expedited review process, during which a voting member of the IRB will consider whether the researcher’s proposed handling of privacy and confidentiality considerations is acceptable.