Overview
At the discretion of the IRB, projects meeting the criteria for exemption under the federal regulations (45 CFR 46) and projects not governed by federal regulations but defined by this institution as meeting Yale University Special Exemption Category 7 as described in IRB Policy 100, IRB Review of Research Proposals, may be granted an exemption following review and written determination by an experienced IRB member, IRB staff reviewer, or appropriately trained University personnel delegated by the IRB to grant exemptions. This procedure describes the requirements and process for review of projects that may qualify for exemption.

Submission Requirements
If an investigator believes that his or her research activities may qualify for exemption, he or she should request such a review by indicating the applicable exemption category on the Exemption Request Template and submit the project to be reviewed via IRES IRB. An experienced IRB member, staff reviewer, or IRB delegate is responsible for ultimately determining, in writing, whether or not a study qualifies or is appropriate for exemption. The exempt determination must not be assumed by the investigator without such formal determination from the IRB or qualified personnel.

Ethical Requirements for Exempt Studies
Studies which are deemed exempt by the IRB are still required to adhere to basic ethical principles regarding the ethical treatment of participants and/or their data. Investigators are expected to design exempt studies so that risks to participants are minimized and justified by the anticipated benefits of the research; where prospective participants are informed about the research and voluntarily agree to participate; participant privacy and confidentiality is protected commensurate with confidentiality risks including appropriate data security; and subject selection is equitable.

Ethical requirements also extend to incidental findings arising in the course of research. Researchers should be prepared to respond to any issues that arise in the course of exempt research to ensure the protection of research participants. For example, observational studies may encounter situations of imminent risk to participants, and tissue-based research may identify risk factors for disease. Researchers should consider the types of incidental findings which could arise in a given project, whether it would be possible to contact participants and then identify appropriate responses, if any. See also IRB Policy 720 and Guidance on Incidental Findings with Possible Health and Safety Significance for Research Participants (Incidental Findings).

Exemption status also does not obviate other obligations of the investigator such as State-mandated reporting requirements for abuse, communicable disease or other applicable state reporting requirements.
Review Process

Research proposals that may qualify for exemption consideration are reviewed by one or more experienced reviewers who may or may not be voting members of the IRB. In no case may a project be reviewed by an individual with a real or perceived conflict of interest in the research. The reviewer will determine whether or not the study meets the exemption categories defined in Policy 100, IRB Review of Research Proposals (see also http://www.hhs.gov/ohrp/policy/checklists decisióncharts.html).

An individual may be considered to be an experienced reviewer following a training period under the direction of the IRB Chair, IRB Manager or senior IRB regulatory analyst in which the individual has demonstrated competence in interpreting the nuances of the exemption categories.

If the research clearly qualifies for exemption, the assigned reviewer will issue an exemption determination in writing to the investigator. If the research does not clearly qualify, or if participants would benefit from continued IRB oversight, the reviewer may refer the study for expedited review or to a meeting of the convened IRB for review. For example, research involving the Psychology subject pool is generally not granted exemption as the recruitment process may lead participants to perceive undue influence. The reviewer also may seek clarification from the principal investigator. The reviewer may suggest changes to the study design so that the study may qualify for exemption from further IRB review.

Applicability of Common Rule and FDA Exemptions

The Food and Drug Administration (FDA) has not adopted all of the exemption categories as described in Policy 100: IRB Review of Research protocols. Exempt status shall not be granted when: Categories (1) through (5) apply and research is subject to FDA regulations. FDA regulated research exemptions are limited to taste and food quality evaluations and emergency use of test articles. Research which is otherwise exempt requires IRB approval and oversight if the research is subject to FDA regulations.

Applicability of Informed Consent Requirements

Obtaining truly informed and voluntary consent to participate in research is a hallmark of research ethics. Even when the research is deemed exempt from further IRB review, it is still appropriate to obtain informed consent from participants unless it is impracticable to do so (see IRB Policy 200: Informed Consent for Human Research). If there are interactions with participants, the consent process should disclose information such as: a statement that the activity involves research; the purpose of the study; a description of the procedures; a statement that participation is voluntary; a statement that there are adequate provisions to maintain the privacy interests of participants; and the name and contact information for the investigator. Depending on the design of the study, the use of a consent form, information sheet or consent script is expected. The IRB will not stamp or watermark its approval of such document, however.

Applicability of HIPAA to Exempt Studies

Studies involving the use or disclosure of protected health information are required to comply with HIPAA Policy 5032: Use and Disclosure of Protected Health Information for Research Purposes in addition to IRB policies. Research projects found to be exempt may still require HIPAA authorization or an IRB approved waiver of HIPAA authorization. For example, studies found to qualify for exemption under 45 CFR 101(b)(2) or (b)(4) because they will not include the collection of direct identifiers such as name or street address may nonetheless include data elements considered to be identifiers under HIPAA such as date of birth or date of service. Investigators should include either a HIPAA authorization or a request for a waiver of HIPAA authorization in the exemption request to the IRB if protected health information will be collected.
Vulnerable Populations

Children
Research involving children may qualify for exemption unless the study involves survey or interview procedures or observation of public behavior where the investigator participates in the activities being observed. (45 CFR 46.401).

Prisoners
Exemptions are not applicable to research involving persons who are currently known to be incarcerated.

Pregnant women and other potentially vulnerable populations
Research involving pregnant women, individuals with impaired consent capacity or other potentially vulnerable populations may qualify for exemption if they meet the criteria described in Policy 100: IRB Review of Research Proposals.

Psychology Subject Pool
Studies recruiting participants through the Psychology subject pool are not granted exemptions as this population 1) may include minors and would be restricted as described above for studies involving children and 2) may perceive undue influence in being recruited in the context of the Introductory Psychology course.

Notification and Documentation Requirements
The reviewer will provide written notification to the investigator regarding the outcome of the review including the exemption category. Investigators will also be informed that changes to the study which would impact the exemption determination are subject to further review by the IRB. The exempt determination must not be assumed by the investigator without formal written determination from the IRB or qualified reviewer. No human subjects’ research may commence until such written exemption determination is provided by the IRB/staff/qualified reviewer to the investigator.

IRB records will include documentation regarding the determination of the permissible category for exemption through a checklist included in the IRB file and in the IRB letter.

A list of all human research protocols determined to be exempt is provided to the IRB members at each convened meeting.

Further Review of Exempt Studies
Once a protocol is determined to be exempt, it is not reviewed again by the IRB unless certain changes are made to the protocol. The IRB will only review changes to exempt studies which may impact the exemption determination initially granted. See Guidance document 100 GD 9: Guidance on Exemption from IRB Review. In such a case, modification request must be submitted to the IRB for further review. After the changes are reviewed, a determination will be made regarding the continued exempt status of the research.

Investigators conducting research involving human participants (exempt or otherwise) are required to report Unanticipated Problems Involving Subjects or Others (UIRISOs) and Adverse Events in accordance with IRB Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events.

There is no continuing IRB review process for exempt research.