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IRB 360 NEWSLETTER

Connecting Research with Ethics

Exempt *vs.* Expedited

Which **review category** should I choose for my study? To differentiate between "*Exempt*" and "*Expedited*" review, please refer to the table below.

Exempt	Expedited
Harm: **Less than minimal risk** study, with virtually no possibility of harm.	**Harm:** **Minimal risk** study, with expected harm ordinarily encountered in daily life.
Participants: Must be **anonymous**, and participants' answers will not reveal their identity in any way**.** E.g. an anonymous online survey which does not collect IP addresses can be considered anonymous.	**Participants:** Involves **identifiable data** from participants. E.g. voice, video, digital, or image recordings, name, IP address, individual email, handphone number
Methodology: Includes research in normal educational settings; anonymous educational tests, surveys, interviews, or public observation; benign behavioural interventions; and taste and food quality evaluations.	**Methodology:** Includes research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
Secondary research on existing (or public) datasets or biological materials in which subjects **cannot be re-identified** (directly or indirectly).	**Secondary research** on existing datasets with identifiable data, or subjects **can be re-identified** from the dataset.
Continuing Review (CR) and Compliance Monitoring (CM): Not required.	**Continuing Review (CR) and Compliance Monitoring (CM):** Required.

Waivers of Informed Consent Requirements

A waiver or alteration to the informed consent procedure **may be allowed** if certain criteria/conditions are met. A waiver is usually allowed for studies of low risk which qualify for review under the "*Exempt*" category.

Waiver of Informed Consent	Waiver of Parental Consent	Waiver for obtaining Written Documentation
• Consent will NOT be sought/obtained. • No consent form will be provided.	• The minor's parent/ guardian consent will NOT be obtained. • Consent/assent taken only from the minor.	• No Documentation of written consent *(e.g. requesting verbal consent).* • Consent form is the only record linking subject to research.

PIs are to provide **protocol-specific justifications** in their IRB applications on how their study meets each of the criteria/conditions required for the waiver. Stating "not applicable" or re-stating the criteria/condition will not be an acceptable response. Please refer to our **guidelines** for more details.

Singapore Research Ethics Conference (SREC)
Navigating Ethical and Regulatory Challenges in the New Era for Human Subject Research

23-25 Nov 2021 via Zoom

Stay tuned for our next newsletter to learn more!

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Refer to our website for more information on **IRB Guidelines** here.