

Reviewers –

Dashboard Studies Submissions Tasks Meetings Reporting More

Cancel Save

Decision: Approved Result Date: 10-23-2023 Administrative Check-In Date: MM/DD/YYYY

Continuing review is mandatory.

Categories

Select the applicable categories for this decision.

- 1a. Research on drugs for which an Investigational New Drug Application (21 CFR Part 312) is not required. (Note: Research on medical devices that significantly increases the risk of or decreases the acceptability of the risks associated with the use of the product is not eligible.)
- 1b. Research on medical devices for which (i) an Investigational Device Exemption Application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy nonpregnant adults (who weigh at least 110 pounds) for these subjects, the amount of venous blood drawn is not more than 10 mL in a 5-day period. This collection may not occur more frequently than 2 times per week.
- 2b. Collection of biological specimens from other subjects, including pregnant women, for research purposes. The amount of blood drawn is not more than 10 mL in a 5-day period. This collection may not occur more frequently than 2 times per week.
- 3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth both if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) unaccumulated saliva collected either in an unstimulated fashion or in a stimulated fashion; (f) urine; (g) sweat; (h) nasal secretions; (i) sputum; (j) tears; (k) sweat; (l) sweat; (m) sweat; (n) sweat; (o) sweat; (p) sweat; (q) sweat; (r) sweat; (s) sweat; (t) sweat; (u) sweat; (v) sweat; (w) sweat; (x) sweat; (y) sweat; (z) sweat.
- 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscle strength testing, body composition assessment, and flexibility testing where appropriate; (f) the use of a device or device that is used in the course of the individual's daily life.

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In-Draft Submission is with researchers Awaiting Authorization Submission is awaiting certification or approval Submission is being prepared for review

Under Review

IRB-FY2024-1 - Board Test Expedited

Review POC Checklist

Routing: Switch Review Complete

Do Not forget to click "Review Complete" - this will be the last step of the reviewer and it will ensure this review will go back to the IRB Analyst.

PI: Frances Faculty Current Analyst: Amy Patel Decision: N/A Policy: Post-2018 Rule Required Tasks: Make Decision

Review Type: Expedited Review Board: Lubbock IRB Meeting Date: N/A

Name	Role	Routing Action	Completion Date
Amy Patel	Analyst	Reviewers Assigned	10-23-2023 9:05 AM
Amy Patel	Analyst	Returned to Assign Reviewers	10-23-2023 9:04 AM
Amy Patel	Analyst	Redo Review	10-23-2023 9:04 AM
Shelby Grey Grubelnik	Primary Reviewer	Review Completed	09-27-2023 1:20 PM
Amy Patel	Analyst	Reviewers Assigned	09-27-2023 8:40 AM
Shelby Grey Grubelnik	Analyst	Review Type/Board Assigned	09-26-2023 9:07 PM
Shelby Grey Grubelnik	Analyst	Analyst Assigned	09-26-2023 9:06 PM
Shelby Grey Grubelnik	Organization Administrator	Approved	09-26-2023 9:05 PM

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