Western Michigan University — Homer Stryker M.D. School of Medicine	**CHECKLIST:** Expedited Review		
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	As a reviewer are you:
☐ Yes ☐ No	An investigator, consultant, collaborator, or study personnel on the proposed study
☐ Yes ☐ No	Do you have a financial interest in the study?
☐ Yes ☐ No	Do you have any other conflict of interests with this study?
If yes, DO NOT perform the review and contact the HRPP/IRB Office at 269.337.4345 or irb@med.wmich.edu	

1 **General Criteria For All Reviews** (All must be **"Yes" or "N/A"**)

☐ **Yes** ☐ **No** ☐ **N/A**	If the research involves prisoners, the prisoner representative has reviewed it. (**"N/A"** if no prisoners as subjects.)

NOTE: Initial or continuing review must meet criteria set 3. Modifications can meet either criteria set 2 or 3.

2 **Minor Modifications** (All must be **"Yes" or "N/A"**)

☐ **Yes** ☐ **No**	The modification does not alter the previously determined overall risks and benefits of the study and does not substantially alter the overall scientific aims or design of the study.
☐ **Yes** ☐ **No**	The modifications add no more than minimal risk[i] to subjects.
☐ **Yes** ☐ **No** ☐ **N/A**	All added procedures fall into categories (1)-(7) below. (**"N/A"** if no added procedures)

3 **Initial Review, Continuing Review, or Modifications** (All Must Be **"Yes"** or **"N/A"**)

☐ **Yes** ☐ **No** ☐ **N/A**	The research activities (or remaining research activities) present no more than minimal risk[ii] to human subjects. (**"N/A"** if the research falls into category (8)(b) or this is for continuing review of a HUD use)
☐ **Yes** ☐ **No** ☐ **N/A**	Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (**"N/A"** if the research falls into category (8)(b) or this is for continuing review of a HUD use)
☐ **Yes** ☐ **No** ☐ **N/A**	The research is **NOT** classified research involving human subjects. (**"N/A"** if this is for continuing review of a HUD use)
☐ **Yes** ☐ **No** ☐ **N/A**	The research falls into one or more of the following categories: **(Check all that apply; "N/A"** if this is for continuing review of a HUD use**)** ☐ (1)(a) Clinical studies of drugs when an IND is not required. ☐ (1)(b) Clinical studies of medical devices that are determined IDE exempt, determined non-significant risk by the FDA or FDA cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling[iii]. ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture[iv] from healthy, non-pregnant adults who weigh >110 pounds where the amount drawn is <550 ml/8 week period and collection occurs ≤2 times/week[v]. ☐ (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (at most <50 ml and <3 ml/kg/8 week period), and the frequency with which it will be collected (at most ≤2 times/week[vi].) ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive means.[vii] ☐ (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.[viii] ☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes. ☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes. ☐ (7)(a) Research on individual or group characteristics or behavior ☐ (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. ☐ (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions[ix]; and (iii) the research remains active only for long-term follow-up of subjects. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)[x] ☐ (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have been enrolled (is interpreted to mean that no subjects have ever been enrolled at a particular institution)and no additional risks have been identified (is interpreted to mean that neither the investigator nor the IRB at a particular institution has identified any additional risks from any institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.)[xi]

	☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)[xii] ☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk[xiii] and no additional risks have been identified.
☐ **Yes** ☐ **No** ☐ **N/A**	This is continuing review of a HUD use [xiv].

4 FINAL DETERMINATION

☐	Modifications required to secure approval:	
	☐	The human research would be approved using the expedited procedure if the following modifications were made:
Delineate modifications required to secure approval:		
☐	What is your final recommendation (include any protocol-specific findings justifying regulatory determinations)?	

5 Continuing Review (for Expedited Review only)

☐	Continuing review not required.
☐	Continuing review required. Rationale:

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[i] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.

[ii] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.

[iii] Note: Use section 6 of the HRP-316 Device worksheet to determine if the medical device is IDE Exempt. Only studies with documentation (letter or email from FDA) as a non-significant risk (NSR) determination made by the FDA qualify for expedited review under this category. Studies with only the sponsor claiming NSR must be sent to the fully convened IRB for review.

[iv] Note: OHRP considers withdrawal of blood from an indwelling venous line to be a "venipuncture."

[v] Note: OHRP considers multiple withdrawals of blood from an indwelling venous line to be more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

[vi] Note: OHRP considers multiple withdrawals of blood from an indwelling venous line to be more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

[vii] Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[viii] 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, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[ix] Note: Research must be limited to only interaction with subjects. No research-related interventions, even if minimal risk, can be conducted in order to qualify under this category.

[x] See http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-e2

[xi] See http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-e2

[xii] See http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-e2

[xiii] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.

[xiv] Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers Document issued on: July 8, 2010 states "46. What types of review functions are IRBs responsible for with respect to HUDs? IRBs are responsible for initial as well as continuing review of the HUD. For initial review of a HUD, IRBs are required to perform their review at a convened meeting (21 CFR 56.108). For continuing review, IRBs may use the expedited review procedures (21 CFR 56.110)."