AdventHealth Orlando

WORKSHEET: Expedited Review

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This worksheet is used to determine whether non-exempt <Human Research> can be reviewed using the expedited procedure.

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1. Exclusion criteria: (If any are true, the research cannot be reviewed using the expedited procedure)

1.1	☐	The research is <Classified Research>
1.2	☐	The research is DOD-regulated and involves <Prisoners> as subjects

2. Risk level (One of the following must be true)

2.1	☐	All of the following are true:		
	2.1.1	☒	The research in its current state presents no more than <Minimal Risk> to subjects, including <Minimal Risk> of criminal or civil liability, or damage financial standing, employability, insurability, reputation, or be stigmatization related to invasion of privacy and breach of confidentiality	
	2.1.2	☐	One of the following is true:	
			○ The research does not involve <Prisoners> as subjects	
			○ A prisoner representative has reviewed the research and concurs with the minimal risk determination	
2.2	☐	The activity falls into (8)(b), (HDE), (MM1), or (MM2)		

3. Categories *63 FR 60364-60367, November 9, 1998*

3.1	☒	Initial or continuing review of research that involves only procedures in one or more of the following:		
	(1)(a)	☐	Clinical studies of drugs for which an IND is not required	
	(1)(b)	☐	Clinical studies on medical devices for which an IDE is not required	
	(2)(a)	☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds, where the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week (see Footnote 1)	
	(2)(b)	☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and <Children>, where the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8 week period and collection may not occur more frequently than 2 times per week (see Footnote 2)	
	(3)	☐	Prospective collection of biological specimens for research purposes by noninvasive means (see Footnote 3)	
	(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 (see Footnote 4)	
	(5)	☒	Research involving materials 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 (see Footnote 5)	
	(7)(b)	☐	Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies	
	(NR)	☐	Research not conducted, supported or otherwise subject to regulation by any US federal department or agency and not FDA-regulated	
3.2	☒	Continuing review of an activity previously approved by the convened IRB where one of the following is true:		
	(8)(a)	☒	The research is permanently closed to the enrollment of new subjects at the site; (ii) all subjects have completed all research-related interventions at the site; and (iii) the research remains active only for long-term follow-up of subjects at the site, where "long-term follow-up" means interactions performed for research purposes that involve no more than minimal risk and collection of private identifiable information from interventions performed for non-research purposes, regardless of whether the interventions are described in the research protocol	
	(8)(b)	☐	No subjects have ever been enrolled at the site and no additional risks have been identified at any site	
	(8)(c)	☐	The remaining research activities at the site are limited to data analysis	
	(9)	☐	The research is not conducted under an investigational new drug application or investigational device exemption, the above categories do not apply, the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk, and no additional risks have been identified at any site	
	(HDE)	☐	The activity is a non-research clinical HDE use (see Footnote 6)	
3.3	☐	Minor modifications of an activity previously approved by the IRB where one of the following is true:		
	(MM1)	☐	All of the following are true:	
		(MM1).1	☐	The modification adds no more than minimal risk to subjects
		(MM1).2	☐	There is no substantial alteration of the research design
		(MM1).3	☐	All added procedures fall into categories (1)-(7) or (NR) above
	(MM2)	☐	The modification is the addition of a site to previously approved research where all of the following are true:	
		(MM2).1	☐	No one associated with the request is flagged in the computer system as "No Expedited Review"
		(MM2).2	☒	The research does not involve consent in an emergency setting
		(MM2).3	☐	All investigators on an IND or IDE study are physicians
		(MM2).4	☐	There are no other issues, which in the opinion of the <Designated Reviewer>, merit convened IRB review

4. Notes

5.	Footnotes
5.1	Each access of a indwelling line is one venipuncture.
5.2	When assessing risk consider the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
5.3	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.
5.4	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.
5.5	Including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior
5.6	*Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers Question* See question and answer 46.