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| --- |
| PI Name: Click here to enter text. |
| Study Title: Click here to enter text. |
| VDSS IRB Study # Click here to enter text. |
| IRB Reviewer Name: Click here to enter text.  |
| Date reviewed: Click here to enter a date. |

Expedited Review of Research

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the expedited categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that

the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Minimal Risk: 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 or during the performance of routine physical or psychological examinations or tests.

Expedited Review Criteria

1. The research is no more than minimal risk.

[ ]  Yes

[ ]  No. If the research is more than minimal risk, it is not eligible for expedited review.

1. The research is not classified (US national security purposes only).

[ ]  Yes

[ ]  No. If the research is classified, it is not eligible for expedited review.

1. Would identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing.

[ ]  Yes

[ ]  No

If yes, have reasonable and appropriate protections implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?

[ ]  Yes [ ]  No (If No, the research is not eligible for expedited review).

Eligible Categories

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| 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)(b) 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. **NOTE: VDSS does not participate in clinical studies.** |[ ]
| 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight week period and collection may not occur more frequently than twice weekly; or(b) from other adults and children, considering 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. For these subjects, the amount drawn may not exceed the of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than twice weekly. |[ ]
| 3. Prospective collection of biological specimens for research purposes by noninvasive means. |[ ]
| 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. |[ ]
| 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) |[ ]
| 6. Collection of data from voice, video, digital, or image recordings made for research purposes. |[ ]
| 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) |[ ]
| 8.Continuing review of research previously approved by the convened IRB as follows:(a) where : (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or,(b) where no subjects have been enrolled and no additional risks have been identified; or,(c) Where the remaining research activities are limited to data analysis. |[ ]
| 9.Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting thatthe research involves no greater than minimal risk and no additional risks have been identified. |[ ]

Determination

Based on the information in the protocol, I have made the following determination(s):

[ ]  The activity is not eligible for expedited review and must be reviewed by the full IRB

[ ]  The activity is eligible for expedited review but should be reviewed by the full IRB

 Reason for full board review: Click here to enter text.

[ ]  The activity is appropriate for expedited review and the review category is checked above.

1. Funding Source

If the study is funded in whole or part by one of the following federal departments, see Guidance Document(s) for additional review requirements.

[ ]  U.S. Department of Justice (DOJ) including the National Institute of Justice

[ ]  U.S. Department of Education (DOE)

[ ]  National Institute on Disability and Rehabilitation Research (NIDRR)

1. Assessment of Protocol

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| --- |
| Is the proposed research scientifically sound? |
| Yes | No | Scientific review criteria |
|[ ] [ ]  The protocol lays out a research proposal which is scientifically sound or has scholarly merit? |
|[ ] [ ]  The research is likely to answer its proposed research question or hypothesis? |
|[ ] [ ]  The available background information supports the appropriateness and adequacy of the proposed research? |
|[ ] [ ]  The sample size and population is appropriate for the proposed research? |
|[ ] [ ]  Adequate time, resources, staffing, etc. exist for the safe and appropriate conduct of this research? |
|[ ] [ ]  Will the research design yield useful data? |
| Other observations about scientific soundness of the protocol?Click here to enter text. |

1. ASSESSMENT OF SUBJECT POPULATION/RECRUITMENT
	1. Is enrollment of subjects equitable?

Yes [ ]  No [ ]

* 1. Is the subject population appropriate for the research?

Yes [ ]  No [ ]

* 1. Are there any vulnerable populations?

Yes [ ]  No [ ]

* 1. If applicable, are appropriate safeguards in place for vulnerable populations?

Yes [ ]  No [ ]

* 1. Is recruitment non-coercive and consistent with all regulations, laws and VDSS guidance documents?

Yes [ ]  No [ ]

1. Assessment of risk
	1. Is this research more than minimal risk?

Yes [ ]  No [ ]

* 1. Are subjects being subjected to unnecessary risks?

Yes [ ]  No [ ]

1. minimalization of Risk
	1. Are adequate provisions in place to minimize research risks? (Examples include frequent monitoring, qualified personnel, response to emergency situations)

Yes [ ]  No [ ]

* 1. Does monitoring include a data safety monitoring board? If appropriate

Yes [ ]  No [ ]

* 1. Should this research be periodically reviewed more frequently than once per year?

Yes [ ]  No [ ]

1. Assessment of anticipated benefits
	1. Is there direct benefit to the subject?

Yes [ ]  No [ ]

* 1. Does research provide therapeutic benefit?

Yes [ ]  No [ ]

* 1. Does this research primarily benefit society (involves procedures performed for research purposes only without direct benefit to subject)/

Yes [ ]  No [ ]

* 1. Is compensation offered to subject?

Yes [ ]  No [ ]

* 1. Do the benefits of this research outweigh the risks?

Yes [ ]  No [ ]

1. informed consent 45 CFR 46.101(b)(5)

|  |  |  |
| --- | --- | --- |
| Yes | No | Item |
|[ ] [ ]  Is the consent form is written in language likely to be understandable to the subject population? |
|[ ] [ ]  Will the potential subject be approached for informed consent in an appropriate manner? An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. 45 CFR 46.116 |
|[ ] [ ]  Is compensation offered to subject? |
|[ ] [ ]  Do the benefits of this research outweigh the risks? |

* 1. Required elements of informed consent

Does the informed consent document include the eight required elements?

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental

Yes [ ]  No [ ]

1. a description of any reasonably foreseeable risks or discomforts to the subject

Yes [ ]  No [ ]

Click here to enter text.

1. a description of any benefits to the subject or to others which may reasonably be expected from the research

Yes [ ]  No [ ]

Click here to enter text.

1. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

Yes [ ]  No [ ]

1. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

Yes [ ]  No [ ]

Click here to enter text.

1. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

Yes [ ]  No [ ]

Click here to enter text.

1. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

Yes [ ]  No [ ]

Click here to enter text.

8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Yes [ ]  No [ ]

Click here to enter text.

1. Privacy/Confidentiality/Data security
	1. Will the P.I. collect sensitive information about the subject?

Yes [ ]  No [ ]

* 1. Are adequate provisions in place to protect privacy/confidentiality?

Yes [ ]  No [ ]

Click here to enter text.

* 1. Will participation be documented in subject’s VDSS case record (including a copy of the consent/assent form(s)?

Yes [ ]  No [ ]

* 1. Is security related to electronic data adequately addressed?

Yes [ ]  No [ ]

 Click here to enter text.

1. Other considerations
	1. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. (45 CFR 46.111(b))

Click here to enter text.

* 1. Is there any conflict of interest for the PI or other study personnel?

Yes [ ]  No [ ]

Click here to enter text.

* 1. If this research is related to a grant or contract, is the information in the grant or contract appropriate and consistent with the research documents submitted to the IRB?

Yes [ ]  No [ ]

Click here to enter text.

**Please provide a narrative summary of any changes/modifications required.**

Click here to enter text.

I recommend:

|  |  |  |
| --- | --- | --- |
|  [ ]  Approval |  [ ]  Modifications required (see my comments above) | Defer: Click here to enter text. |