Oklahoma State University Institutional Review Board Standard Operating Procedures		
Initial Expedited Review	SOP #	RR 403
	Effective Date	1/1/2012
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	Revision #	1
	Approval: IRB	05/14/2014

1. POLICY

An expedited review procedure consists of a review of research involving human subjects by the Chair of the IRB or by one or more experienced reviewers designated by the Chair from among members of the IRB without convening a meeting of the full IRB. The IRB Chair has delegated the day-to-day duty of distributing research applications qualifying for expedited review to the IRB Manager and IRB Coordinator, who disseminate the applications based on the experience and expertise of the respective IRB members.

The categories of research that may be reviewed by the IRB through an expedited review procedure include 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 categories authorized by 45 CFR 46.110 and listed in section 1.1 of this policy.

Specific Procedures

1.1 Determining Expedited Review Status

The expedited review procedure may not be used when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' 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. Furthermore, the expedited review procedure may not be used for classified research involving human subjects.

1.1.1 Definition of Minimal Risk

Minimal risk is defined as "...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" (45 CFR 46.102(i)

1.1.2 Expedited Research Categories

The activities listed herein should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this 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.

1.1.2.1 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.

1.1.2.2. 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 8 week period and collection may not occur more frequently than 2 times per week; 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 lesser of 50 ml or 3 ml per kg of body weight in an 8 week period and collection may not occur more frequently than 2 times per week.

1.1.2.3. Prospective collection of biological specimens for research purposes by noninvasive means. For example:

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
j. washings;
k. sputum collected after saline mist nebulization;
l. vaginal swabs that do not go beyond the cervical os;
m. rectal swabs that do not go beyond the rectum; and
n. nasal swabs that do not go beyond the nares.

1.1.2.4. 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 medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples include:

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.

1.1.2.5. 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.)

1.1.2.6. Collection of data from voice, video, digital, or image recordings made for research purposes.

1.1.2.7. 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.)

1.1.2.8. 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.

1.1.2.9. 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 that the research involves no greater than minimal risk and no additional risks have been identified.

The expedited review procedure may not be used with human subjects research involving prisoners.

1.2 Submission

1.2.1 The Investigator makes a preliminary determination that a research application (herein after referred to as IRB application or an application) is eligible for expedited review based on the categories presented in 1.1 of this document. IRB office personnel make the final determination regarding whether an application qualifies for expedited review, with input from the IRB Chair when appropriate.

1.2.2 The Investigator submits one (1) original copy of a completed IRB application form requesting review at the expedited level to the IRB Office, which is housed in the Office of University Research Compliance (URC).

1.2.3 Upon receipt of the application form it is entered into the IRB electronic tracking system and assigned an IRB number by the IRB Coordinator.

1.3 Pre-Review

1.3.1 Applications that request expedited review will be evaluated by the IRB Coordinator, the IRB Manager, or the IRB Chair (or his/her designee), who will determine if the project qualifies for expedited review.

1.3.2 If the application does not meet the criteria for expedited review, the IRB Manager or IRB Coordinator will change and initial the review designation on the application form, which will be processed for review at the appropriate level.

1.3.3 The IRB Coordinator or IRB Manager will distribute each application to a qualified reviewer based on criteria established by the IRB Chair. Reviewers are assigned based on their experience and expertise in the area of research proposed in the application and on any required special representation. If no members of the board possess the required expertise, the IRB Manager or IRB Chair will solicit an external reviewer to serve as a consultant to the IRB member reviewing the application and the IRB.

1.3.4 The IRB Coordinator prepares review materials to be distributed to each reviewer. The reviewer receives a transmittal email with the desired return date, a complete copy of the application, the appropriate IRB Member Review Sheet to document the reviewer's review and decision regarding approval. The IRB Reviewer Guide and the Expedited Review Categories form is also provided to the reviewer. These are sent to each reviewer via email. The reviewer is given seven days to review the application and respond.

1.4 Review

1.4.1 The expedited reviewer exercises all of the authority of the IRB except that the reviewer may not disapprove research. The IRB may only disapprove a research application in accord with the non-expedited review procedures set forth in federal regulations 45 CFR 46.108(b). Any one reviewer may request review of an application by the IRB at a convened meeting.

1.4.2 The reviewer must return a copy (electronic or hard copy) of the IRB Member Review Sheet with his/her approval decision and any comments to the IRB Manager or IRB Coordinator.

1.5 Review Outcomes

1.5.1 The reviewer makes one of the following recommendations by completing the IRB Member Review Sheet:

> Approved: The research procedures and associated documents meet the criteria for approval with no further revision needed.
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> Approved with Conditions: The research procedures and associated documents meet the criteria for approval with no further revision needed. However, final approval is pending receipt of external documentation as specified (i.e., school permissions, other committee approvals, second IRB approval documentation, etc.).
>
> Pending Revision: Minor revisions which do not involve substantive issues must be made before the research can be approved. The Investigator(s) must submit the revisions for review.
>
> Designated for full board review: The reviewer determines that the application should be reviewed at a convened meeting of the IRB.

1.5.2 The approval period for the application is determined at the time of review. The approval period will be appropriate to the degree of risk, but no longer than one year. The following factors are considered in determining the criteria for which applications require review more frequently than one year and what the review frequency will be:

> Probability and magnitude of anticipated risks to participants;
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> Specific experience of the investigator(s) and other members of the research team in conducting similar research;
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> Nature and frequency of adverse events observed in similar research;

Vulnerability of the subjects;

Any other factors the IRB deems relevant.

The start of the approval period (i.e. approval date) is the date the approval letter is generated by the IRB Coordinator or IRB Manager using the IRB electronic tracking system.

1.5.3 When an application is placed in pending revision status, the IRB Coordinator will document the approval status and any suggested revisions for the reviewer in the tracking system. Upon approval by the IRB Manager, the IRB Coordinator will generate an email message to the Investigator(s) transmitting the revisions requested by the IRB.

1.5.4 The Investigator is responsible for submitting any requested revisions to the IRB. The IRB Manager or IRB Coordinator reviews the response to the request for revisions to determine if the investigator's response is appropriate. If the response is deemed appropriate, the IRB Coordinator or IRB Manager documents that the application is approved in the tracking system.

1.5.5 If the IRB Manager or IRB Coordinator determines that the revisions are inappropriate or insufficient, the Investigator(s) will be asked to make further revisions. The original reviewer of the application will be involved as necessary. This review and revision process will continue until the application is approved at the expedited level or reassigned to a different review level (i.e. exempt or full board).

1.5.6 When an application is approved with conditions, the IRB Coordinator or IRB Manager will generate a "provisionally approved" letter to be sent to the Investigator(s) stipulating the documents that are needed prior to final approval. Upon receipt of the requested documentation, an approval letter will be issued as described in 1.5.7.

1.5.7 When an application is approved, the IRB Coordinator or IRB Manager will generate the approval letter for IRB Chair signature and attach all recruiting, consent, and debriefing documents with the IRB approval stamp affixed with the valid dates of IRB approval.

1.5.8 If the investigator has concerns regarding the IRB decision/recommendations for changes in the research, he/she may submit his/her concerns to the IRB reviewer, if known to him/her, and/or the IRB Chair via a written document that includes justification for changing the IRB decision. The reviewer and the Chair will agree on a final resolution. If the investigator is still dissatisfied with the IRB decision, the application will be sent to the convened IRB for review.

1.6 Notification of the IRB

Expedited review of all applications, modifications and continuations is documented monthly by the IRB Coordinator and is made available to all members via the IRB web distribution site and presented to the board at the next convened meeting.

2. SCOPE

This procedure applies to all research submitted to the IRB that qualifies for expedited review.

3. RESPONSIBILITY

The Investigator is responsible for submission of the IRB application for expedited review and for responding to any revisions requested by the reviewer in a timely manner.

The IRB Coordinator is responsible for receiving applications from Investigators requesting expedited review, evaluating applications for sufficient information and verifying expedited review status, preparing and distributing the review package to the IRB member serving as the expedited reviewer, tracking the application review process and any revisions in the IRB

tracking system, sending any revision requests to investigators, reviewing revision responses, and generating approval letters.

The IRB Manager is responsible for verifying expedited review status, changing the review level to exempt or full board when appropriate, assigning and/or soliciting reviewers as delegated by the IRB Chair, reviewing suggested revisions from the expedited reviewers, reviewing and approving investigator responses to revisions and generating approval letters.

The IRB Chair is responsible for oversight of the expedited review process and provides guidance and assistance as needed. The Chair receives all written concerns from investigators regarding IRB decisions or recommendations and coordinates meetings to assist in their resolution.

4. APPLICABLE REGULATIONS AND GUIDELINES

Minimal Risk:

45 CFR 46.102

21 CFR 56.102

Expedited Review:

45 CFR 46.110

21 CFR 56.110

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other IRB SOPs.

6. ATTACHMENTS

RR 403 Expedited Review Applicability and Categories

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
IRB Coordinator	Receive application submissions, review for sufficient information, verify expedited review status, complete tracking database entry, confirm that investigator has completed required training, prepare and send review packages, and track the application review process.	RR 403- Expedited Review Applicability and Categories
IRB Manager	Verify review status, change review level designation when appropriate, assign or solicit reviewers, review suggested revisions from reviewers, review and approve investigator responses, and generate approval letters.	RR 403- Expedited Review Applicability and Categories

IRB Chair	Provide oversight of the expedited review process, provide guidance and assistance to IRB Manager and IRB Coordinator on review level as needed and requested.	RR 403- Expedited Review Applicability and Categories
IRB Member	Perform primary review; using all the appropriate worksheets.	RR 403- Expedited Review Applicability and Categories RR 402A - IRB Reviewer Guide, RR-402-B-G IRB Review Sheet(s)
IRB Coordinator	Receive reviews from IRB members, enter the information into the tracking system.. Upon approval by the IRB Manager, send review comments to Investigator(s). Review response from investigator(s) to determine if requested revisions have been satisfactorily addressed.	
IRB Manager	Review reviewer revision request and add to suggested revisions as necessary. Review response from investigator(s) to determine if requested revisions have been addressed satisfactorily and if so, approve investigator responses.	
IRB Coordinator	Generate correspondence notifying Investigator of application approval status (approved, pending revision, approved with conditions, or designated for full board review), document outcome in tracking database. If application was placed in pending or conditional approval status, upon approval of revisions, or requested documentation, update approval status in tracking database and generate correspondence notifying Investigator.	
IRB Chair	Receive and review written concerns from Investigator(s) regarding IRB decisions or recommendations. Coordinate meetings for resolution. Assist IRB Manager and IRB Coordinator as needed.	

Applicability

(A) 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 following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this 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.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' 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.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) Reviewers are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(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.

(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 8 week period and collection may not occur more frequently than 2 times per week; or
>
> (b) from other adults and children[2], 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 lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

a. 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 gumbase 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; (k) vaginal swabs that do not go beyond the cervical os; (l) rectal swabs that do not go beyond the rectum; and (m) nasal swabs that do not go beyond the nares.

(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 medical 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, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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 that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.