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CPHS REVIEW CHECKLIST

CRITERIA FOR APPROVAL

		Yes	No	N/A
1.	**Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.**			
	Consider physical, psychological, social, economic and legal risks. Consider whether procedures are consistent with sound research design. Evaluate whether the research plan uses procedures already being performed on the participants for diagnostic or treatment purpose, if applicable.			
2.	**Risks to participants are reasonable in relationship to the potential benefits, if any, to participants, and the importance of the knowledge that may be expected to result.**			
	Consider only those risks and benefits that may result from the research. Consider the likelihood and magnitude of the risks. Do not consider possible long-range effects of applying knowledge gained in the research as among those research risks. Consider which risks to subjects would be present anyway and which risks are related to the research. Review potential benefits to subjects –benefits that would be present anyway and benefits related to the research. Consider the importance of the knowledge that will result.			
3.	**Participant selection is equitable.**			
	Evaluate inclusion criteria and exclusion criteria. Consider how will subjects be recruited. Evaluate whether research burdens are distributed fairly and whether research benefits are distributed fairly. Consider if vulnerable subjects will be recruited.			
4.	**Informed Consent is obtained and documented.**			
	Consider who will obtain consent and who will give consent for participation. Examine any conflicts of interest and adequacy of relevant management plan. Evaluate whether written consent document is accurate and complete and embodies the required and appropriate additional elements (see below). Consider whether participant will have adequate opportunity to read the consent document before it is signed. Consider whether the participant or the participant's legally authorized representative will sign and date the consent document. Consider if a copy of the signed and dated consent document will be given to the person signing the document. Consider whether consent discussion will occur in a language with which the participant is comfortable.			
5.	**For research involving more than minimal risk to participants, there is adequate provision for monitoring the data collected to ensure the safety of participants.**			
	Consider whether participation in the research involves greater than minimal risk to subjects. If yes, a data and safety monitoring plan is required. Determine if safety and efficacy data will be reviewed and if so, who will review data. (Investigator, DSMB, Independent Physician, etc.) Review the frequency of monitoring and consider whether the plan includes appropriate stopping criteria – futility, safety and efficacy.			
6.	**If appropriate, there are adequate provisions to protect the privacy of participants.**			
	Consider the plan proposed to approach potential participants (recruitment strategy). Consider where the consent process will occur – will this be in a private setting.			

7.	**If appropriate, there are adequate provisions to maintain the confidentiality of the data.** Consider whether data collected is to be restricted to that required for research. Consider the plan for storing the data – physical and electronic security, access control. Consider the plan for disposing of the data after the end of the research and appropriateness of records retention period.	**Yes**	**No**	**N/A**
8.	**When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect rights and welfare of these participants.** Consider whether inclusion of any vulnerable population is justified. Consider whether appropriate additional protections are in place for any vulnerable populations. For greater than minimal risk research, consider whether there is a prospect of direct benefit to individual subjects. Consider whether subjects are capable of giving consent, and if not, who will consent on behalf of the subject.	**Yes**	**No**	**N/A**
9.	**The study has the resources necessary to protect participants.** Consider whether the investigators have adequate time to conduct and complete the research. Consider whether the research staff are qualified. Consider if the facilities are adequate.	**Yes**	**No**	**N/A**

CPHS REVIEW CHECKLIST

INFORMED CONSENT CHECKLIST

Basic elements of Informed Consent			
1. A statement that the study involves research An explanation of the purposes of the research The expected duration of the subject's participation A description of the procedures to be followed, Identification of any procedures which are experimental.	Yes	No	N/A
2. A description of any reasonably foreseeable risks or discomforts to the subject.	Yes	No	N/A
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.	Yes	No	N/A
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.	Yes	No	N/A
5. A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained notingthe possibility that the regulatory authorities, IRB, and sponsor's monitors may inspect the records.	Yes	No	N/A
6. For research involving more than minimal risk, an explanation as to whether any compensation for injury is provided 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	N/A
7. An explanation of whom to contact for answers to questions: ▪ about the research and research subjects' rights, ▪ in the event of a research-related injury to the subject ▪ in the event of complaints about research.	Yes	No	N/A
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	Yes	No	N/A

Additional Elements of Informed (when applicable)			
1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable.	Yes	No	N/A
2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.	Yes	No	N/A
3. Any additional costs to the participant that may result from participation in the research.	Yes	No	N/A
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.	Yes	No	N/A
5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.	Yes	No	N/A
6. The approximate number of participants involved in the study.	Yes	No	N/A
7. A statement that CPHS has reviewed and approved the protocol, including the protocol tracking number.	Yes	No	N/A
8. A statement regarding the possibility of sharing study results with participants.	Yes	No	N/A

For more information refer to CPHS policy on Informed Consent.

CPHS REVIEW CHECKLIST

Informed Consent Process			
1. Appropriate individuals will obtain informed consent.	Yes	No	N/A
2. Appropriate individuals will provide informed consent. (consent from Legally Authorized Representative only when appropriate)	Yes	No	N/A
3. Method of obtaining consent is appropriate (in person, telephone, internet)	Yes	No	N/A
4. Environment is conducive (may not be appropriate to approach a subject immediately before a procedure or surgery, while in labor, while under sedation and any other situation where a subject might feel compromised.)	Yes	No	N/A
5. Subjects will be given adequate time to make a decision.	Yes	No	N/A
6. The investigator has provided an adequate plan that minimizes the possibility of coercion or undue.	Yes	No	N/A
7. The information to be communicated to the subject or the legally authorized representative does not include exculpatory.	Yes	No	N/A
8. Appropriate plans for non-English speaking subjects.	Yes	No	N/A

For more information refer to CPHS policy on Informed Consent.

CPHS REVIEW CHECKLIST

EXPEDITED REVIEW CHECKLIST

Applicability Criteria

To qualify for review by expedited process, a research proposal must meet the following criteria:

- The research proposal presents no more than minimal risk to human subjects, Yes No N/A
- Identification of subjects and / or their responses does not reasonably place them at risk of criminal or civil liability, or damage to their financial standing, employability, insurability, reputation, and is not 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, Yes No N/A
- The research is not classified, and Yes No N/A
- The research activity is listed in the Categories of Review below: Yes No N/A

Expedited Review Category

Category 1: Clinical studies of drugs and medical devices only when either of the following conditions are met.

- Research on drugs for which an investigational new drug application 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.)
- Research on medical devices for which;
  - An investigational device exemption application is not required; or
  - The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- From healthy, non-pregnant adults who weigh at least 50 kg. For these participants, 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
- From other adults and children, considering the age, weight and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- 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;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and sub-gingival 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;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization;

- **Category 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 a medical device are not generally eligible for expedited review, including studies of

cleared medical devices for new indications).

- 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 participant or an invasion of the participant's privacy.
- Weighing or testing sensory acuity.
- Magnetic resonance imaging (without contrast or gadolinium).
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate, given the age, weight, and health of the individual.

Category 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).

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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 groups, program evaluation, or quality assurance methodologies.

For more information refer to CPHS policy Expedited Review.

CPHS REVIEW CHECKLIST

SPECIFIC REGULATORY DETERMINATIONS

Research Involving Drugs and Biologics

If there is an IND number listed in the application:

- Check validity (FDA letter or Sponsor Protocol)
- Who holds the IND – Sponsor / UT Houston Investigator / Non UT Houston Investigator

If no IND number has been provided

- Evaluate PI's justification on why IND is not required.

Review the question on drug storage in Study Drug Details section and if the MHH Investigational Drug Service is not responsible for drug storage and dispensing – review the investigator's plan for drug storage.

For more information refer to CPHS policy Investigational Drugs.

Research involving devices

If there is an IDE number listed in the application:

- Check validity (FDA letter or Sponsor Protocol)
- Who holds the IDE – Sponsor / UT Houston Investigator / Non UT Houston Investigator

If no IDE number has been provided:

- Check if PI has submitted FDAs SR/NSR determination.
- If no FDA letter, check if sponsor has submitted SR/NSR determination.
- IRB must determine SR/NSR status if FDA letter not provided.

For more information refer to CPHS policy Investigational Devices.

Research Involving Children

Review information on panel on Children and investigator's plan for parental permission and/or assent.

IRB must determine whether the research can be approved under one of the following categories:

- Category 404 – No greater than minimal risk. Permission from one parent may be sufficient.
- Category 405 – Greater than minimal risk with prospect of direct benefit to the child participating. CPHS may find that the permission of one parent is sufficient.
- Category 406 – Minor increase over minimal risk with no prospect of direct benefit to the child participating. Permission of both parents required unless one parent has legal custody or one parent is deceased, unknown, incompetent or reasonably unavailable.

For more information refer to CPHS policy Research Involving Children.

Research Involving Pregnant Women

If the research will include pregnant women, check to confirm if the panel for pregnant women has been filled out.

IRB needs to determine whether all the conditions of subpart B have been met:

- Determine if the research holds out:
  - prospect of direct benefit to the pregnant woman.
  - prospect of a direct benefit both to the pregnant woman and the fetus.
  - no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- Whether consent is obtained in accord with the informed consent provisions according to regulations.
- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with regulations.
- For children who are pregnant, assent and permission are obtained according to state regulations for emancipation.

For more information refer to CPHS policy Research Involving Pregnant Women.

Research Involving Prisoners

The research must be permissible under the following categories:

- A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
- A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.
- Epidemiologic studies whose sole purposes are either (i) to describe the prevalence or incidence of a disease by identifying all cases or (ii) to study potential risk factor associations for a disease.

For more information refer to CPHS policy on Research Involving Prisoners.

Waiver of Consent

CPHS may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided that CPHS finds and documents that

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- Whenever appropriate, the participants will be provided with additional pertinent information after participation;
- The research is not subject to FDA regulation.

For more information refer to CPHS policy on Informed Consent

Waiver of Documentation of Informed Consent

CPHS may approve waiver of documentation of informed consent. CPHS must determine that:

- That all of the following are true (only for non FDA research):
  - The only record linking the participant and the research would be the consent document.
  - The principal risk would be potential harm resulting from a breach of confidentiality.
  - Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.
- That all of the following are true (for both FDA regulated and non FDA research):
  - The research presents no more than minimal risk of harm to participants.
  - The research involves no procedures for which written consent is normally required outside the research context.

For more information refer to CPHS policy on Informed Consent

Problem Reports

The expedited reviewer or convened IRB must determine whether the problem:

- Is an unanticipated problem involving risks to subjects or others.

For more information refer to CPHS policy on Reporting Problems.; CPHS Responsibilities Reporting.

Protocol Deviations or Noncompliance Reports

The expedited reviewer or convened IRB must determine whether the incident:

- Is a serious and/or continuing noncompliance.

For more information refer to CPHS policy on Noncompliance.

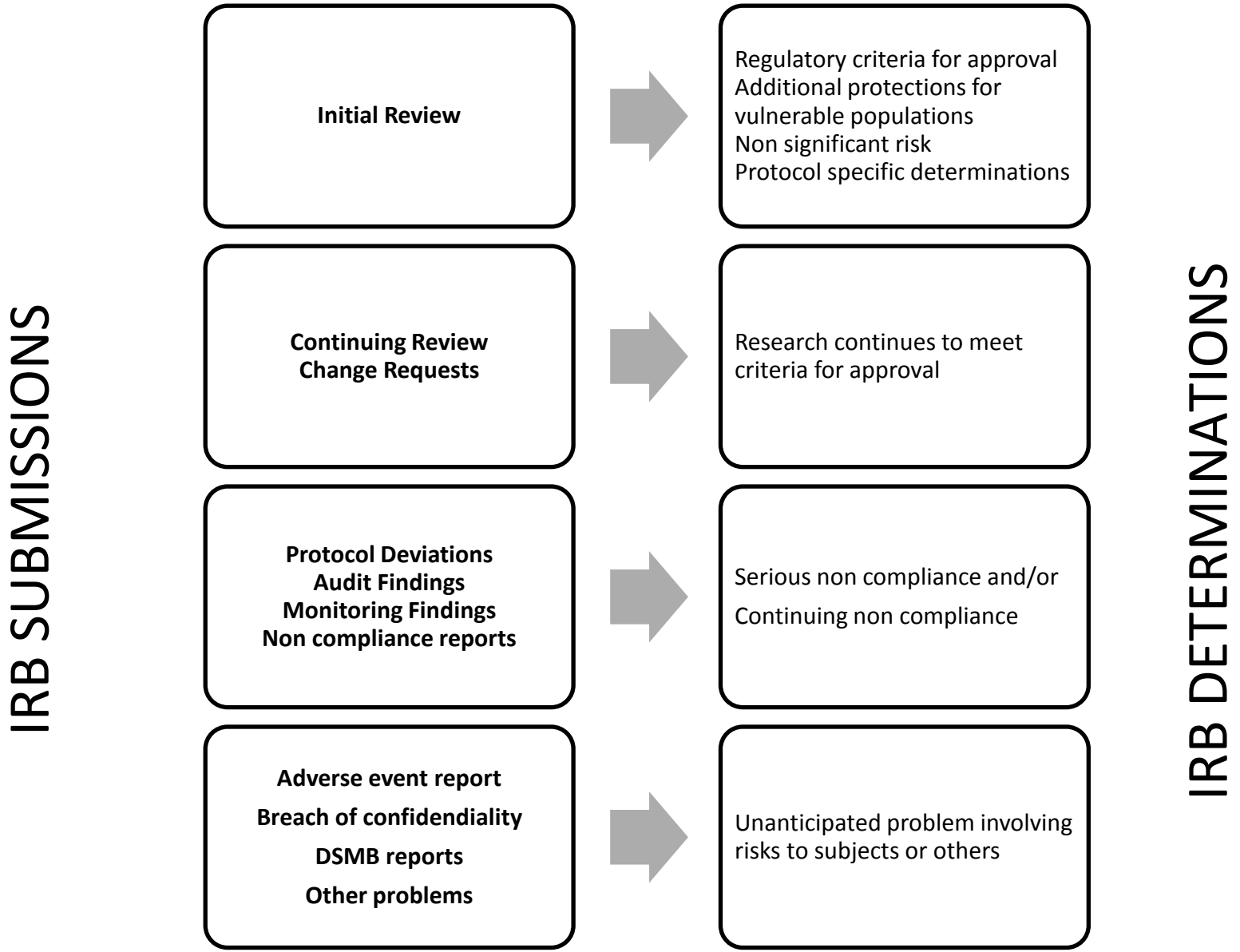
CPHS REVIEW CHECKLIST

Research Supported by Department of Defense

- If the research involves greater than minimal risk, CPHS may require the investigator to appoint of a medical monitor by name. The medical monitor has the authority to stop a research study, stop participation of individuals in a research study, take steps to protect safety and well-being of participants until review by an IRB.
- If the research is classified, the research must be reviewed by convened board and must have prior approval from the Secretary of Defense.
- The research must have undergone scientific review. Substantive amendments must have prior scientific review.
- If the investigator requests to obtain consent from legally authorized representatives:
  - Research must have prospect of benefit to participants.
  - Subject lacks capacity to consent.
- If the investigator is seeking waiver of consent:
  - Research must have prospect of benefit to participants.
  - Waiver of consent has been approved by head of the DoD component.
- If the research involves military personnel:
  - Officers are not permitted to influence the decision of their subordinates.
  - Officers and senior non-commissioned officers may not be present at the time of recruitment and have a separate opportunity to participate.
  - When recruitment involves a percentage of a unit, an independent ombudsman is present.
  - Participants are not permitted to receive payment of compensation for research during duty hours.
- Research involving Prisoners of wars – not approvable.
- If the research involves multiple sites a formal agreement between organizations is required to specify the roles and responsibilities of each party.
- If research involves surveys of Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

Research Supported by Department of Education

- If the research is being conducted at a school – approval from the school district should be in file.
- In general, written permission from the parent or eligible student in order to release any information from a student's education record. IRB may grant a waiver if all personal identifiers are removed.
- If the research involves surveys, no student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
  - Political affiliations.
  - Mental and psychological problems potentially embarrassing to the student or his or her family.
  - Sex behavior and attitudes.
  - Illegal, anti-social, self-incriminating, and demeaning behavior.
  - Critical appraisals of other individuals with whom the student has close family relationships.
  - Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
  - Religious practices, affiliations, or beliefs of the student or student's parent.
  - Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.
- If the research purposefully includes of children with disabilities or individuals with mental disabilities as research participants and is specifically funded by the National Institute on Disability and Rehabilitation Research, the IRB is required to include at least one person primarily concerned with the welfare of these research participants during the review process.


IRB SUBMISSIONS
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Additional protections for vulnerable populations
Non significant risk
Protocol specific determinations
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Serious non compliance and/or
Continuing non compliance
Unanticipated problem involving risks to subjects or others
IRB DETERMINATIONS