

IRB PROTOCOL REVIEW STANDARDS

Regulatory review requirement for IRB discussion and documentation in the meeting minutes. For full, expedited and modifications

1. Risks (physical, psychological, social, legal, economic) to subjects are minimized by using procedures consistent with sound research design & which do not unnecessarily expose subjects to risk.
2. Risks to subjects are minimized whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.
3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, **and** the importance of knowledge that may reasonably be expected to result.
4. Subject selection is equitable.
5. Informed consent is obtained from research subjects or their legally authorized representative(s) as follows:
 - The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
 - The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
 - The circumstances of consent minimize the possibility of coercion or undue influence.
 - The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.
 - No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
 - All required & appropriate additional disclosures will be provided to the participant or participant's representative. (*See Elements of Informed Consent Disclosure*)
6. Informed consent will be appropriately documented.
 - The consent document embodies the basic and appropriate additional elements of disclosure. (*See Elements of Informed Consent Disclosure*)
 - The participant or the participant's legally authorized representative will sign and date the consent document.
 - A copy of the consent document will be given to the person signing the consent document.
 - The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

OR

 - If short form written consent will be used, see short form checklist.
7. If research involves more than minimal risk, there are adequate provisions for monitoring the data collected to ensure the safety of subjects
8. There are adequate provisions to protect the privacy of participants.
9. There are adequate provisions to maintain the confidentiality of the data.

Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.

- If the research involves pregnant women, fetuses, or neonates use *Research Involving Pregnant Women and Fetuses* OR *Research Involving Neonates* checklist.
- If the research involves prisoners use *Research Involving Prisoners* checklist.
- If the research involves children use *Research Involving Children* checklist.
- If the research involves adults unable to consent use *Research Involving Adults unable to Consent* checklist.

Additional Considerations All Reviews: Does the IRB have the scientific or scholarly expertise, the representational experience, knowledge of the local context, and other expertise needed to review this research? If not, obtain consultation or review by another IRB.

Additional Considerations Initial Review: **1)** Should review be obtained more often than annually? If yes, be sure IRB Staff captures correctly. **2)** If this is multi-site research, is the management of information that might be relevant to the protection of subjects adequate? If no, add contingencies.

Additional Considerations Continuing Review: **1)** Should review be obtained more often than annually? If yes, be sure IRB Staff captures correctly. **2)** Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review? If yes, describe. **3)** Is the consent document accurate and complete? If no, add appropriate contingencies. **4)** If information has arisen that might affect willingness of participants to continue in the research, will it be provided to those participants? If not, add contingencies.

Additional Considerations Modifications To Previously Approved Research: If information has arisen that might affect willingness of participants to continue in the research, will it be provided to those participants?

Additional considerations	
1. Ionizing radiation.	<p>If ionizing radiation is used in this protocol does it present increased radiation exposure over the current standard of care?</p> <p>If so, has the increased exposure been disclosed in the consent in lay terms?</p> <p>Has the Radiation Safety Committee approved the study?</p>
2. Collaborative research.	<p>Is this domestic/international collaborative research? If so, are FWAs or other assurances required for the sites involved?</p> <p>Are other sites relying on the UAMS IRB of record? If so, is there an IRB Authorization Agreement?</p>
3. FDA-regulated research	See Addendums for Drugs and Devices
4. Students	<p>Will students be recruited through general advertisements rather than individual solicitations?</p> <p>Does consent process or form state that the subjects can refuse to participate or withdraw early without affecting their academic standing at UAMS?</p>
5. Cognitively Impaired	<p>Has the protocol or SOP outlined how the subject's ability to provide consent will be assessed initially and during the course of the research?</p> <p>Are there provisions for obtaining LAR signature if subject is not capable of providing consent?</p> <p>If LAR required, should "assent" of subject also be obtained?</p>
6. Pregnant Women, Fetuses, and Neonates	See Addendum
7. Prisoners	See Addendum
8. Children and Wards	See Addendum
9. Waiver of consent, Waiver of Documentation	See Addendum

Elements of Informed Consent Disclosure		
A statement that the study involves research.	An explanation of the purposes of the research.	An explanation of the expected duration of the participant's participation.
A description of the procedures to be followed.	Identification of any procedures which are experimental. <i>(May be omitted if there are none.)</i>	A description of any reasonably foreseeable risks or discomforts to the participant. <i>(May be omitted if there are none.)</i>
A description of any benefits to the participant or to others, which may reasonably be expected from the research. <i>(May be omitted if there are none.)</i>	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. <i>(May be omitted if there are none.)</i>	A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. <i>(May be omitted if confidentiality will not be maintained.)</i> UAMS IRB, other institutional oversight offices and the Office for Human Research Protections must be listed. As applicable, any other outside agencies such as a sponsor or funding source should also be listed.
A statement that notes the possibility that the Food and Drug Administration may inspect the records. <i>(May be omitted for research that is not FDA-regulated.)</i>	Mandated reporter disclosure <i>(May be omitted if no member of the study team is a mandated reporter.)</i>	An explanation as to whether compensation is available if injury occurs. <i>(May be omitted if the research involves no more than minimal risk.)</i>
If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. <i>(May be omitted if the research involves no more than minimal risk.)</i>	An explanation as to whether any medical treatments are available if injury occurs. <i>(May be omitted if the research involves no more than minimal risk.)</i>	If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. <i>(May be omitted if the research involves no more than minimal risk.)</i>
An explanation of whom to contact for answers to pertinent questions about the research.	An explanation of whom to contact for answers to pertinent questions about the research participants' rights.	An explanation of whom to contact in the event of a research-related injury to the participant. <i>(Note: May not be omitted just because the research involves no more than minimal risk.)</i>
Contact information for the research team for questions, concerns, or complaints.	Contact information for someone independent of the research team for problems, concerns, questions, information, or input.	A statement that participation is voluntary.
A statement that no rights have been waived by signing the consent form.	A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.	A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
The approximate number of participants involved in the study, locally and nationally.	Age range for participants to be studied.	The amount and schedule of all payments to the participant.

Additional elements to be provided when appropriate

<p>A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. <i>(Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)</i></p>	<p>A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. <i>(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)</i></p>	<p>Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. <i>(Look for when the protocol mentions this as a possibility.)</i></p>
<p>Any additional costs to the participant that may result from participation in the research. <i>(Look for when additional costs are expected.)</i></p>	<p>The consequences of a participant's decision to withdraw from the research. <i>(Look for when withdrawal from the research will have adverse consequence.)</i></p>	<p>Procedures for orderly termination of participation by the participant. <i>(Look for when such procedures are part of the protocol.)</i></p>
<p>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. <i>(Look for on long-term clinical trials.)</i></p>	<p>Yes/No option for future use of samples if data or specimens will be stored for future use.</p>	<p>Notice that participant and AR DOH will be notified of positive test results if study is testing for HIV or communicable diseases. If HIV, participants should also be given information about counseling options.</p>
<p>Other Information</p>		
<p>Each page is numbered, dated and includes version number.</p>	<p>Each page lists the Title, Sponsor and Institution</p>	<p>Written at a level understandable to all participants.</p>
<p>No statements similar to "Compensation will not be provided." (No exculpatory language.)</p>	<p>Appropriate Signature/Date/Time lines. There should not be a signature line for legally authorized representative or parent, when the research is not approved for cognitively impaired adults or children.</p>	

Short Form Written Consent

The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.

A written summary embodies the basic and appropriate additional elements of disclosure.

There will be a witness to the oral presentation.

For participants who do not speak English, the witness is conversant in both English and the language of the participant.

The participant or the participant's legally authorized representative will sign and date the consent document.

The witness will sign both the short form and a copy of the summary.

The person actually obtaining consent will sign a copy of the summary.

A copy of the short form will be given to the participant or the representative.

A copy of the summary will be given to the participant or the representative.

Research Involving Children

Be prepared to discuss each section at the meeting so that discussion and rationale can be captured in minutes.

1) Level of Risk

<ul style="list-style-type: none"> ● No greater than minimal risk (Cat. 1) 	Must provide rationale:
<ul style="list-style-type: none"> ● Greater than minimal risk with prospect of direct benefit. (Cat. 2) More than minimal risk to children is presented by: <ul style="list-style-type: none"> ○ An intervention or procedure that holds out the prospect of direct benefit for the individual subject OR ○ A monitoring procedure that is likely to contribute to the subject's well-being. <p style="text-align: center;">IRB must also find that</p> <ul style="list-style-type: none"> ○ The risk is justified by the anticipated benefit to the subjects AND ○ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternatives. 	Must provide rationale for each choice: Is the permission of one parent sufficient? Provide rationale:
<ul style="list-style-type: none"> ● Greater than minimal risk with NO prospect of direct benefit but likely to yield generalizable knowledge about the subject's disorder or condition. (Cat. 3) More than minimal risk to children is presented by: <ul style="list-style-type: none"> ○ An intervention or procedure that does not hold out the prospect of direct benefit for the individual subject OR ○ A monitoring procedure which is not likely to contribute to the subject's well-being. <p style="text-align: center;">IRB must also find that</p> <ul style="list-style-type: none"> ○ The risk represents a minor increase over minimal risk; AND ○ The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; AND ○ The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. 	Must provide rationale for each choice: Both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
<ul style="list-style-type: none"> ● Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (Cat. 4) 	Must consult with HHS or FDA before approval.

2) Parental permission.

<ul style="list-style-type: none"> ● Adequate provisions are made for soliciting the permission of each child's parents or guardians. Select one: <ul style="list-style-type: none"> <input type="checkbox"/> The permission of each child's parents or guardian will be obtained unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. <input type="checkbox"/> The permission of one parent is sufficient even if both parents are alive, known, competent, reasonably available, and share legal responsibility for the care and custody of the child. (Not allowed if the research involves Categories 3 or 4 or the the permission of one parent is inconsistent with state law) <p style="text-align: center;">OR</p> ● The study is not a FDA regulated study and parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) AND there is an appropriate mechanism for protecting the children who will participate as subjects in the research. <p style="text-align: center;">FDA does not allow waiver of parental permission.</p>	Provide rationale:
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3) Assent of children. The IRB shall take into account the ages, maturity and psychological state of the children involved.

- IRB has determined that all children are capable of assenting. **OR**
- IRB has determined that some children are capable of assenting. (Must state requirements.) **OR**
- IRB has determined that assent is not required.

The IRB determines that assent is not a requirement of **some or all** children because:

- The children are not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children is so limited that they could not reasonably be consulted.
- The assent can be waived using the criteria for waiver of informed consent. ● IRB has determined that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children AND is available only in the context of the research.

When the IRB determines that assent is a requirement:

- The IRB determined whether assent will be documented.
- If so, the IRB determines the process to document assent.

Provide rationale:

Research Involving Prisoners

Be prepared to discuss each section at the meeting so that discussion and rationale can be captured in minutes.

Definition: "Prisoner" is defined as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Examples:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

Note: If research is conducted or supported by HHS, the IRB must certify that it reviewed the research and that it made the seven findings required by the regulations.

1. Does the research fall into one of the following **categories of permissible research**? If it does not, prisoners may not be involved in the research.
 - A.** The research involves the study of the possible causes, effects, and process of incarceration, and of criminal behavior **AND** the research presents no more than minimal risk and no more than inconvenience to the participants.
 - B.** The research involves the study of prisons as institutional structures or of prisoners as incarcerated persons **AND** the research presents no more than minimal risk and no more than inconvenience to the participants.
 - C.** The research is 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) **PROVIDED** the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research.
 - D.** The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research.
 - E.** The sole purposes of the research are to either describe the prevalence or incidence of a disease by identifying all cases **OR** to study potential risk factor associations for a disease **AND** the research presents no more than minimal risk and no more than inconvenience to the prisoner-participants **AND** prisoners are not a particular focus of the research.

Provide Rationale:

2. Any **possible advantages** accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired.

Provide Rationale:

3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.	Provide Rationale:
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal.	Provide Rationale:
5. The information is presented in language that is understandable to the subject population.	Provide Rationale:
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole , and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.	Provide Rationale:
7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.	Provide Rationale:

Research Involving Pregnant Women and Fetuses

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.	State reasons.
2. One of the following is true: <ul style="list-style-type: none"> ○ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. ○ There is no prospect of direct benefit for the woman or the fetus BUT the risk to the fetus is not greater than minimal, AND the purpose of the research is the development of important biomedical knowledge AND the biomedical knowledge cannot be obtained by any other means. 	State reasons.
3. Any risk is the least possible for achieving the objectives of the research.	State reasons.
4. One of the following is true: <ul style="list-style-type: none"> ○ The research holds out the prospect of direct benefit to the pregnant woman AND the woman's consent will be obtained. ○ The research holds out the prospect of direct benefit both to the pregnant woman and the fetus AND the woman's consent will be obtained. ○ The research holds out no prospect of benefit for the woman or the fetus AND the 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 AND the woman's consent will be obtained. ○ The research holds out the prospect of direct benefit solely to the fetus AND the consent of the pregnant woman and the father will be obtained. Exception - Father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity or the pregnancy resulted from rape or incest. 	State reasons.
5. Each individual providing consent is full informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.	State reasons.
6. One of the following is true: <ul style="list-style-type: none"> ○ Research will not include any pregnant children. ○ Research involves children who are pregnant AND all requirements for research involving children are met. 	State reasons.
7. No inducements, monetary or otherwise will be offered to terminate a pregnancy.	State reasons.
8. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.	State reasons.
9. Individuals engaged in the research will have no part in determining the viability of a neonate.	State reasons.

Research involving Neonates of Uncertain Viability	
1. The research involves neonates where it will not be ascertained whether a neonate is viable.	State reasons.
2. Either of the following are true: <ul style="list-style-type: none"> ○ Preclinical and clinical studies to provide data for assessing potential risks to neonates are not scientifically appropriate. ○ Preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. 	State reasons.
3. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.	State reasons
4. Individuals engaged in the research will have no part in determining the viability of a neonate.	State reasons
5. Either of the following are true: <ul style="list-style-type: none"> ○ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability AND any risk is the least possible for achieving that objective. ○ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means AND there will be no added risk to the neonate resulting from the research. 	State reasons
6. Either of the following are true: <ul style="list-style-type: none"> ○ The legally effective informed consent of either parent of the neonate is obtained. Exception: The consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. ○ If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative will be obtained. Exception: The consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. 	State reasons
Research involving Non-Viable Neonates	
1. The research involves neonates ascertained to be non-viable.	State reasons
2. Either of the following are true: <ul style="list-style-type: none"> ○ Preclinical and clinical studies to provide data for assessing potential risks to neonates are not scientifically appropriate. ○ Preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. 	State reasons
3. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.	State reasons
4. Individuals engaged in the research will have no part in determining the viability of a neonate.	State reasons
5. Vital functions of the neonate will not be artificially maintained.	State reasons
6. The research will not terminate the heartbeat or respiration of the neonate.	State reasons
7. There will be no added risk to the neonate resulting from the research.	State reasons
8. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.	State reasons
9. The legally effective informed consent of both parents of the neonate will be obtained. (Exception: The consent of the father need not be obtained if the pregnancy resulted from rape or incest.) The informed consent of one parent will suffice if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity. Note: The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.	State reasons
Research involving Viable Neonates	
Research involving neonates ascertained to be viable should meet all the requirements for Research Involving Children (Subpart D).	

Drug Checklist (If multiple drugs used in research, need to consider each drug.)

<ul style="list-style-type: none"> ○ The drug has a valid IND. 	<p>Note what document was looked at to verify the validity of the IND number.</p> <ul style="list-style-type: none"> ○ Protocol; ○ Written communication from sponsor; or ○ Written communication from the FDA if UAMS holds the IND.
<p align="center">Research is exempt from the requirement for an IND if one of the following is true:</p>	
<ul style="list-style-type: none"> ○ Exemption for approved drugs. In order to meet this all of the following must be true: <ul style="list-style-type: none"> ● The drug being used in the research is lawfully marketed in the U.S. ● The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug. ● The research is not intended to support a significant change in the advertising for the product. ● The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. ● The research is conducted in compliance with FDA requirements for IRB review and informed consent. ● The research does not request a waiver from the requirement for informed consent. ● The research is conducted in compliance with all of the following <ul style="list-style-type: none"> ● The sponsor or investigator, or any person acting on behalf of the sponsor or investigator will not represent in a promotional context that the investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. ● The sponsor or investigator will not commercially distribute or test market the drug. ● The sponsor will not unduly prolong an investigation after finding that the results of the investigation appear to establish sufficient data to support a marketing application. ● The sponsor will not charge for the drug in the clinical trial without the prior written approval of the FDA. 	
<ul style="list-style-type: none"> ○ Exemption for in vitro diagnostic biological products. In order to meet this, all of the following must be true: <ul style="list-style-type: none"> ● The research involves one of the following <ul style="list-style-type: none"> ● Blood grouping serum ● Reagent red blood cells ● Anti-human globulin ● The article will be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure. ● The article is shipped in compliance with §312.160 	
<ul style="list-style-type: none"> ○ Exemption for placebo use. The study is limited to use of a placebo. 	
<ul style="list-style-type: none"> ○ FDA determination of exemption: The research has been submitted to the FDA who determined in writing that an IND is not required. 	

Device Checklist (If multiple devices used in research, need to consider each device.)

<ul style="list-style-type: none">○ The device has a valid IDE.	Note what document was looked at to verify the validity of the IDE number. <ul style="list-style-type: none">○ Protocol;○ Written communication from sponsor; or○ Written communication from the FDA if UAMS holds the IDE.
<ul style="list-style-type: none">○ The device meets the requirements for an abbreviated IDE.<ul style="list-style-type: none">● The medical device is not a significant risk device because all of the following are true:<ul style="list-style-type: none">○ The medical device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.○ The medical device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subjects.○ The medical device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.○ The medical device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.● The medical device is not banned.● The sponsor has presented the reviewing IRB with a brief explanation of why the medical device is not a significant risk device, and maintains such approval.● The sponsor will comply with the requirements of §812.46 with respect to monitoring investigations.● The sponsor will maintain the records required under §812.140(b)(4) and (5) and make the reports required under §812.150(b)(1)-(3) and (5) – (10).● The sponsor ensures that participating investigators maintain the records required by §812.140(a)(3)(i) and make the reports required under §812.150(a)(1),(2), (5), and (7).●The sponsor will comply with the prohibitions in §812.7 against promotion and other practices.●All of the following are true:<ul style="list-style-type: none">○ The participant or the participant’s representative will date the consent document.○ Consent documents include a statement that notes the possibility that the FDA may inspect the records.○ The requirement for informed consent will not be waived.○ The requirement to obtain written informed consent will not be waived because the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.	
<ul style="list-style-type: none">○ Research is exempt from the requirement for an IDE if one of the following is true:	
<ul style="list-style-type: none">● Exemption 1. In order to meet this all of the following must be true:<ul style="list-style-type: none">● The medical device was in commercial distribution immediately before May 28, 1976.● The FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976.● The medical device is being used or investigated in accordance with the indications in labeling in effect at that time of commercial distribution	
<ul style="list-style-type: none">● Exemption 2. In order to meet this, all of the following must be true:<ul style="list-style-type: none">● The medical device was in commercial distribution immediately before May 28, 1976.● The FDA has determined the medical device to be substantially equivalent to a medical device in commercial distribution immediately before May 28, 1976.● The FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976.● The medical device is being used or investigated in accordance with the indications in labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.	
<ul style="list-style-type: none">● Exemption 3. In order to meet this, all of the following must be true:<ul style="list-style-type: none">● The medical device is a diagnostic device.● The sponsor will comply with applicable requirements in §809.10(c).● The testing is noninvasive.● The testing does not require an invasive sampling procedure that presents significant risk.● The testing does not by design or intention introduce energy into a subject.	

• The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established, diagnostic product or procedure.

• **Exemption 4:** In order to meet this, all of the following must be true:

• A medical device undergoing one of the following:

○ Consumer preference testing

○ Testing of a modification

○ testing of a combination of two or more medical devices in commercial distribution.

• The testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

• **Exemption 5:** The medical device is intended solely for veterinary use.

• **Exemption 6:** The medical device is shipped solely for research on or with laboratory animals and labeled in accordance with §812.5(c).

• **Exemption 7:** The medical device is NOT being used to determine safety or effectiveness for commercial distribution **AND** is a custom device because all of the following are true:

• The medical device necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist.

• The medical device is not generally available to, or generally used by, other physicians or dentists.

• The medical device is not generally available in finished form for purchase or for dispensing upon prescription.

• The medical device is not offered for commercial distribution through labeling or advertising.

• One of the following is true:

○ The medical device is to be made in a specific form for that patient.

○ The medical device is intended to meet the special needs of the physician or dentist in the course of professional practice.