**Full Review Form**

**Principal Investigator (PI) Information:**

|  |  |
| --- | --- |
| Name of PI:        | School/Department:       |
| Email Address:       | Phone Number:       |
| PI Status: [ ]  Faculty [ ]  Adjunct Faculty [ ]  Graduate Student [ ]  Undergraduate Student [ ]  Staff [ ]  Other (Specify:      ) |
| Protection of Human Subjects Training:[ ]  Date of Completion:      [ ] Additional Training, Date of Completion:      Please include a copy of completion certificate with this application. Completion Date must be within past three years. Please note that anyone that will be interacting with human participants in addition to the PI should have completed training. |

**For Sponsored Projects (required when the PI is a student):**

|  |  |
| --- | --- |
| Supervising Faculty:        | School/Department:       |
| Email Address:       | Phone Number:       |

**Project Information:**

|  |
| --- |
| Project Title:       |
| Type of Project: [ ]  Individual Research Project [ ]  Class Project [ ]  Thesis/Dissertation[ ]  Other:       |

**Does this research involve minors?** [ ]  Yes [ ]  No

**Does this research involve other vulnerable populations (i.e., prisoners, individuals with impaired decision-making abilities)?** [ ]  Yes [ ]  No

**Purpose**:

Provide a summary of the objectives and significance of this research. Include your hypotheses.

**Background and Justification:**

a) Explain the background of this project, so that we will understand why it is important to perform this research project.

b) Summarize previously published data and pilot studies. Be sure to include a discussion of any data that does not support the study hypothesis. If a study similar to the one being proposed has already been completed, explain why the proposed study is necessary.

c) For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternative modes of therapy.

 d) If not obvious, explain why human participants are necessary. Include references for all published data cited.

**Participants:**

Provide a complete description of your participants. Include an estimated total number of participants, a detailed description of the population they will be recruited from, and a detailed description of how they will be recruited. List all of your inclusion/exclusions criteria and how these criteria will be assessed.

Please note that according to federal guidelines, election of subjects must be equitable. Any exclusion of participants based on sex, race, etc. must be justified and a rationale provided.

If you are recruiting employees or students of Caldwell University please also fill out section A.

If you are recruiting illiterate participants, also fill out section B.

If you are recruiting minors, also fill out section C

If you are recruiting prisoners, also fill out section D.

If you are recruiting people with impaired decision-making ability, also fill out section E.

If you are recruiting pregnant women or women of child-bearing age, also fill our section F.

Please submit all recruitment materials with this application.

**Timetable:**

How long are participants expected to be involved in the study?

Approximately how long do you expect it will take to enroll enough participants to complete the study?

**Compensation:**

Provide a complete description of how and when participants will be compensated for participation. Also include plans for compensation of incomplete participation.

**Methodology:**

Will this study use any **medical device(s)** (a device being studied for medical purposes that does not interact chemically with the body)? [ ]  Yes [ ]  No

If yes, explain:

Will this study use any **investigational drug(s**) (including but not limited to prescription, over-the-counter drugs, herbal remedies)? [ ]  Yes [ ]  No

If yes, explain:

Will this study use any **food products**? [ ]  Yes [ ]  No

If yes, explain:

Have you asked the participant about any allergies to substances being used in this research?

[ ]  Yes [ ]  No. If yes, explain:

Provide a complete description of your design, data collection procedures, measures, materials, and analysis. This section should be detailed and provide a clear picture of everything a participant will experience. Use graphs and flow charts to describe the process if necessary. Make sure to define any terms and concepts that someone outside the field would not know. Also include an analysis plan, including all hypothesis tests (e.g., t-test, chi-square), and estimation methods related to the primary endpoint. Justify your sample size, using the concepts of power, Type I error and effect size, if applicable.

If you are including a placebo as part of your research study, also fill out section G.

Please submit copies of all questionnaires, surveys, or other materials and measures with this application.

**Risks and Benefits:**

Describe any potential risks (physical, psychological, social, legal, financial, or other) and assess their likelihood and seriousness. Describe the procedure for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Please list risks from most severe/likely to least severe/unlikely.

Describe any potential benefits that may come from participation in the study and assess their likelihood.

Describe why the risks to participants are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing the study.

**Data and Safety Monitoring:**

Describe plans for data and safety monitoring to ensure the safety of participants. As described in federal regulations **“**... a variety of types of monitoring may be anticipated depending on the nature, size, and complexity of the trial. In many cases, the principal investigator would be expected to perform the monitoring function.” This will include monitoring to determine: The progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

**Confidentiality:** Please provide a complete description of how confidentiality will be maintained before, during, and after data collection

**Research Sites:**

List all the sites where data collection will take place.

Include permission letters from all external sites with this application.

**Does your study involve transferring identifiable information and/or biospecimens to and/or from a European Country (e.g., an online survey open to participants in Europe)**

 [ ]  Yes [ ]  No

If yes describe how you will meet the requirements set by the European Union on the transfer of data:

**Consent Process:**

Explain what type of consent you will be using (e.g., signed paper, signed electronic, etc.) and provide a complete description of how you will be consenting and documenting consent by participants/legal guardian (e.g., where, how, will you allow questions, will they receive copies of the consent form, etc.).

If you are requesting a waiver or alteration of the typical consent process involving a documented and signed consent form, also fill out section H.

Please submit all consent/assent documents with this application. If you are collecting health information, include the health information permission form.

Will you be obtaining broad consent? [ ]  Yes [ ]  No

If yes, describe your process for obtaining and keeping track of who has and has not provided broad consent.

Note that broad consent requires a separate consent process.

**Financial Considerations:**

Full disclosure of financial impact on the participant is critical to an informed consent. Insurance CANNOT be billed for research-related costs falling outside the standard of care and/or already covered by sponsor dollars. Either the department or participant is responsible for research-related costs not paid for by the sponsor and not billable to insurance. Participants must know which tests, visits, or procedures will be billed to either them or their insurance and which ones will be covered by the study sponsor/department.

List all additional tests/visits/procedures performed for research purposes only. (i.e., those falling outside the standard of care would not be performed if the patient were not a participant and therefore would not be billable to third party payers such as Medicare.)

List items that may be standard care but are paid for by the sponsor:

Will the sponsor be responsible for the above costs? [ ]  Yes [ ]  No

If No, describe who will be responsible (i.e., department or participant).

**Responsibility for costs of injury or illness related to research:**

Will the sponsor be responsible for costs of injury or illness related to the
research? [ ]  Yes [ ]  NoIf applicable, describe whether or not the sponsor will be responsible for device removal if required:

**If the sponsor will not be responsible for costs of injury or illness related to research please complete:**

The reason for no liability:

Summary of potential risks as related to potential costs which could be incurred as

a result of research-related injury or illness:
Describe reason(s) for request of Caldwell University to provide coverage for

research-related injury or illness (which is not standard Caldwell University policy):

**Conflicts of Interest:**

Under IRB policy, a potential conflict of interest occurs when an individual's personal or private interests might lead an independent observer reasonably to question whether the individual's professional actions or decisions are influenced by considerations of personal interest, financial or otherwise. To enable the institutions to determine whether the proposed research would raise a conflict of interest, please respond to the questions below. For purpose of these questions, *“Principal Investigator and Other Key Personnel”* shall mean a Principal Investigator and any other person (including students) who is responsible for the design, conduct, or reporting of research involving human participants.

**Does the Principal Investigator or Other Key Personnel, or any of their spouses, domestic partners, or dependent children, hold any financial or other interest that would reasonably appear to affect or be affected by the proposed research, including but not limited to the following:**

Compensation for services (e.g., consulting fees or honoraria), or in-kind payments, other than from the researcher's primary employer, in the prior calendar year or projected over the next twelve months? [ ]  Yes [ ]  No

Royalty income or the right to receive future royalties under a patent license or copyright, where the proposed research is directly related to the licensed technology or work? [ ]  Yes [ ]  No

Equity interests (e.g. stocks, stock options or other ownership interests, including equity holdings where the value cannot readily be determined by reference to public prices)? [ ]  Yes [ ]  No

Intellectual property rights (e.g., patents, copyrights, royalties from such rights)? [ ]  Yes [ ]  No

Gifts or funds available to the researcher from this sponsor beyond the current research project?[ ]  Yes [ ]  No

Funding expected to significantly exceed the projected costs of conducting the current research project? [ ]  Yes [ ]  No

Membership on the IRB of Caldwell University? [ ]  Yes [ ]  No

Any other financial or personal interest which presents an actual or perceived conflict of interest?[ ]  Yes [ ]  No If yes, describe the financial interests and the parties who would benefit from such interests:

Note: The above list of financial interests does not include: salary and benefits from Caldwell University; income from seminars, lectures, teaching engagements or publishing sponsored by Federal, state, or local entities or from non-profit academic institutions, where the origin of the funds is not from corporate sources; income from service on advisory committees or review panels for governmental or non-profit entities; investments in publicly-traded mutual funds; or gifts and promotional items of nominal value, and meals and lodging for participation in professional meetings.

If you answered yes to any of the questions on conflict of interest, please fill out Attachment I.

**Attachment A**

**Employees and Students of Caldwell University**

One of the primary responsibilities of the IRB is to ensure that a participant’s decision to participate in research will be voluntary and that consent will be sought “only under circumstances that provide the prospective participant... sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.” Students and employees may be vulnerable to “subtle inducements to participate”.

Please describe your rationale for recruiting this population and how recruitment will take place (process and timing):

Another special consideration for employee and student populations is the issue of confidentiality of research data. Depending on the nature of the research and the data collected, a break of confidentiality could affect a person’s employment, career path, educational plans, or social relationship with the hospital/academic community.

Please describe the measures in place to protect participant identity and research data (e.g., coding, storage of research files, limits of accessibility to research data, etc.):

**Attachment B**

**Illiterate Participants**

Participants who are unable to read should not be excluded from research on the grounds of illiteracy. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written consent form and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial, and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative

Please describe the measures you will take to comply with the process described above:

**Attachment C**

**Minors**

**Section 1. Check the risk designation as you deem appropriate. This will be discussed and confirmed by the IRB.**

**[ ]  1.** Research not involving greater than minimal risk *[45 CFR 46.404].
Caldwell University will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parent or guardians, as set forth in 46.408.
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.

**[ ]  2.** Research involving greater than minimal risk but presenting the prospect of direct benefit. *Caldwell University will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual participant, or by a monitoring procedure that* ***is likely to*** *contribute to the participant’s well-being, only if the IRB finds that:
a) the risk is justified by the anticipated benefit to the participants;
b) the relation of the anticipated benefits to the risk is at least as favorable to the participants as that presented by available alternative approaches [45CFR 46.405]*

**[ ]  3.** Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participants’ disorder or condition.

*Caldwell University will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by intervention or procedure that does not hold out the prospect of direct benefit for the individual participant, or by a monitoring procedure which* ***is not likely to*** *contribute to the well- being of the participant, only if the IRB finds;*

*a) the risk represents a minor increase over minimal risk; b) the intervention or procedure presents experiences to participants that are reasonably commensurate
with those inherent in their actual or expected medical, dental, psychological, social or educational situations;*

*c) the intervention or procedure is likely to yield generalizable
knowledge about the participants' disorder or condition which is of vital importance for the understanding of the participants condition [45CFR 46.406].*

**[ ]  4.** Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

*Caldwell University will conduct or fund research that the IRB does not believe meets the requirements of 404, 405, 406. (See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)*

*Only if : a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children; and b) the panel of experts must also find that the research will be conducted in accordance with sound ethical principles [45 CFR 46.407].*

**Section 2. Check the appropriate category of parental/legal guardian consent**. **This will be discussed and confirmed by the IRB.**

**[ ]** One active parental/legal guardian consent for research designated (1) 404 or (2) 405 above.

**[ ]** One active parental/legal guardian consent required for research designated (3) 406 or (4) 407 above, approvable if 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

**[ ]** Parental/legal guardian consent waived (see Attachments H)

**[ ]** Two parental/legal guardian active consent required. (e.g. if the research is designated (3) 406 or (4) 407 above both parents must give their permission 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

**Section 3. Assent of Minor. This will be discussed and confirmed by the IRB.**

In determining whether children are capable of assenting, take into account the ages, maturity, and psychological state of the children involved. If it is determined that the research holds out a prospect of direct benefit, the assent of the children is not a necessary requirement, but should be obtained when possible.

It is important the PI includes the minor in all aspects of the research as appropriate for his/her maturity level. Include copies of any assent documents with this application.

Will you be obtaining assent? **[ ]** Yes **[ ]** No

If yes, describe your assent process:

If no, justify why assent is not necessary:

**Attachment D**

**Prisoners**

Biomedical or behavioral research may involve **prisoners** as participants only if:

(1) The Institutional Review Board has approved the research under §46.305; and in cases of research supported by or conducted by DHHS, the institution has certified to the Secretary [Secretary of Health and Human Services] that the Institutional Review Board has approved the research under §46.305.

and

(2) The proposed research involves solely the following:

(i) 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 subjects;

(ii) 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 subjects;

(iii) 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) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

Except as provided in the above, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Research studies involving **prisoners** can only be approved by the IRB if the following requirements of federal regulations are satisfied:

**(**1) The research under review represents one of the categories of research permissible with prisoners.

(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 such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(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 to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(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; and

(7) Where the Board 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.

(b) In the case of research supported or conducted by DHHS, the Board shall carry out such other duties as may be assigned by the Secretary.

(c) In the case of research supported or conducted by DHHS, the institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

**Section 1. Justification**

Justify the need to use prisoners in this research study, and describe what category of research permissible with prisoners the study falls under.

**Section 2. Risks and Benefits.**

Describe any possible risks and benefits prisoners would face as a result of participation. Justify why any benefits are not disproportionate to the risks faced and will not impair a prisoner’s ability to weight those risks. Also describe how these risks would be different from those undertaken by nonprisoners.

Described recruitment procedures and how equity will be maintained in selection. Otherwise, justify the procedures used for selection.

Describe how information will be conveyed to the participants, and how care will be taken so that they understand risks and benefits, and that participation will not influence parole decisions.

Describe any follow-up examinations or care that participants may need, and describe the provisions that will be taken for this care.

**Attachment E**

**Participants with Impaired Decision-Making Ability**

When a participant has impaired decision-making abilities, Federal Regulations state that the investigator must obtain written permission from a **legally authorized representative** prior to enrolling the participant in a research study. Federal Regulations define **legally authorized representative** as an "individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research" (45CFR46.102(c)). Federal Regulations do not provide specific information about who may or may not qualify as a **legally authorized representative** in a research setting. For the purposes of this policy statement, the options of defining a legally authorized representative include:

a) Durable power of attorney for health care (DPAHC), b) Court appointed legal guardian, or
c) Next-of-kin.

Even with the permission of a DPAHC, or court appointed legal guardian, the IRB will not permit a participant who is not competent to give informed consent to participate in a research study that offers little chance of DIRECT BENEFIT to the research participant over what they could receive outside the research setting and involves a meaningful increase in the risk of harm or discomfort, regardless of the potential gain to future participants or society in general.

**Complete the following sections:**

**Section 1: Risks and Benefits**

Does participating in this study offer the participant a chance of direct benefit over what they could receive outside the research setting? **[ ]** Yes **[ ]** No

If yes, explain:

Is there an increase in the risk of harm or discomfort for the participant over what they would experience outside the research setting? **[ ]** Yes **[ ]** No

If yes, explain:

When there is a meaningful chance of DIRECT BENEFIT to the research participant over what they could receive outside the research setting, the IRB will make a judgment decision about who may consent to participation in the study. The options include: DPAHC, court appointed legal guardian, and a properly motivated next-of-kin.

**Section 2. Check the appropriate category party providing consent**. **This will be discussed and confirmed by the IRB.**

**[ ]** Durable power of attorney for health care (DPAHC)

**[ ]** Court appointed legal guardian
**[ ]** Next-of-kin.

**If a study requests the use of Next-of-Kin as the legally authorized representative, please complete a) through e) below:**Could the participant receive the same management that they will receive in the research study outside the setting of a research protocol? **[ ]** Yes **[ ]** No

If yes, explain:

Will participation in the study increase the risk of harm or discomfort compared to what is expected with the management that the participant will receive if they do not participate in the research study? **[ ]** Yes **[ ]** No

If yes, explain:

Will participating in the study increase the chance that the participant will experience a favorable outcome compared to what is expected with the management that the participant will receive if they do not participate in the research study? **[ ]** Yes **[ ]** No

If yes, explain:

What is the magnitude of the benefit that future patients, or society in general, may experience as a result of the participant participating in this study?

The process of appointing a legal guardian may take several months. Would this type of delay compromise patient care?

**Attachment F**

**Pregnant Women and/or Women of Child-Bearing Ability**

**Pregnant Women:**

Research studies involving **pregnant women or fetuses** can only be approved by the IRB if the following requirements of federal regulations are satisfied:

-Preclinical studies have been conducted, including studies on pregnant animals; clinical studies, that include nonpregnant women and provide data for assessing potential risks to pregnant women and fetuses

-Risk to fetus is caused solely by interventions or procedures that hold prospect of direct benefit for the woman or the fetus or,

-If no benefit, risk to the fetus is not greater than minimal and the research develops important biomedical knowledge not obtainable by any other means.

-Any risk is the least possible for achieving the objectives of the research.

-Individuals engaged in the research will have no part in: 1) any decisions as to the timing, method, or procedures used to terminate a pregnancy, and 2) determining the viability of the fetus at the termination of the pregnancy; and

-No inducements, monetary or otherwise, will be offered to terminate the pregnancy.

Drug research using pregnant people as subjects is governed by the federal regulations. In accordance Federal Regulations, "no pregnant woman may be involved as a subject in a human clinical research project unless:

(1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or

(2) the risk to the fetus is minimal."

Research involving pregnant women is permitted only if the mother and the father are legally competent and both have given their consent after having been fully informed regarding the possible impact on the fetus, except that the father's consent need not be secured if

(1) the purpose of the activity is to meet the health needs of the mother;

(2) his identity or whereabouts cannot be reasonably ascertained;

(3) he is not reasonably available; or

(4) the pregnancy resulted from rape

**Section 1. Justification.**

Does the research study qualify as biomedical in nature? **[ ]** Yes **[ ]** No

Identify the category of permissible research and justify the need to include pregnant people:

**Section 2. Risks and Benefits.**

Identify all risks and benefits to the woman or fetus and justify any potential risks as necessary.

Confirm that all individuals associated with the research will have no part in: 1) any decisions as to the timing, method, or procedures used to terminate a pregnancy, and 2) determining the viability of the fetus at the termination of the pregnancy; and will offer no inducements, monetary or otherwise, to terminate the pregnancy.

**Women of child bearing capability**

Are women of child bearing capability eligible for enrollment into this study? **[ ]** Yes **[ ]** No

*If yes*, describe potential harm to unborn fetus and process for determination of pregnancy. If a pregnancy test is required, note who will pay. If there is potential harm to an unborn fetus, the investigator should review with each man/woman his/her plans to avoid pregnancy. If the investigator regards these strategies to avoid pregnancy as inadequate, the man/woman should be advised on how to make them adequate or should be excluded from the study.

*If no*, explain and include process for determination of pregnancy. If a pregnancy test is required, note who will pay.

**Attachment G**

**Placebo**

Discuss the ethical implications of using a placebo/control group in this situation. Describe and cite what the standard is for this population and how the use of placebo or being in a control group involves risks for participants. Please also address:

a) the safety and efficacy of other available therapies (if any)

b) the maximum total length of time a participant may receive placebo on study

c) the greatest potential harm that may come to a participant as a result of not receiving effective therapy (immediate or delayed onset)

d) protocols in place to safeguard participants

**Attachment H**

**Alteration or Waiver of Consent Process**

**Alteration or Waiver of Consent Process**

In order for an IRB to waive or alter the consent process, the IRB must also find and document that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Describe how you are planning to waive or alter the consent process.

Using the guidelines described above, justify the need to waiver or alter the consent process. Confirm that the waiver/alteration will not adversely affect the rights of participants. If pertinent information will be provided at some point in the research, describe when and how.

**Waiver of Documentation of Consent**

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Justify the need for the IRB to waive the requirement for the documentation of consent. If a written statement about the research will be provided, describe that process.

**Attachment I**

**Conflict of Interest**

Please complete this form and describe financial or other interests held by the Principal Investigator, other key personnel, or any of their spouses, domestic partners, and/or dependent children.

You do not need to include: salary and benefits from Caldwell University; income from seminars, lectures, teaching engagements or publishing sponsored by Federal, state, or local entities or from non-profit academic institutions, where the origin of the funds is not from corporate sources; income from service on advisory committees or review panels for governmental or non-profit entities; investments in publicly-traded mutual funds; or gifts and promotional items of nominal value, and meals and lodging for participation in professional meetings.

**Complete the following:**

Compensation for services (e.g., consulting fees or honoraria), or in-kind payments, other than from the Reporting Person's primary employer, in the prior calendar year or projected over the next twelve months. **[ ]** Yes **[ ]** No

Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work **[ ]** Yes **[ ]** No

Equity interests (e.g. stocks, stock options or other ownership interests, including equity holdings where the value cannot readily be determined by reference to public prices) **[ ]** Yes **[ ]** No

Intellectual property rights (e.g., patents, copyrights and royalties from such rights) **[ ]** Yes **[ ]** No

Gifts or funds available to the researcher from this sponsor beyond the current research project **[ ]** Yes **[ ]** No

Funding expected to significantly exceed the projected costs of conducting the current research project **[ ]** Yes **[ ]** No

Membership on IRB of Caldwell University **[ ]** Yes **[ ]** No

Any other financial or personal interest which presents an actual or perceived conflict of interest. **[ ]** Yes **[ ]** No

If the response to any item is YES, please provide below a full description of the financial or other interest (including amount of compensation and other information related to compensation) and how the financial interest might affect or be affected by the proposed research. (Attach extra pages if necessary.)

Please be advised: current expectations are that your financial relationship with this commercial entity will be routinely disclosed for presentations or publications.

**Assurances:**

I, the investigator (and if applicable, the faculty sponsor), certify that to the best of my knowledge the research described above qualifies for expedited review under 45 CFR§46.110). I agree that any changes to the project will be submitted to the Institutional Review Board before they are implemented, and that any adverse events will be reported in a timely manner. I also recognize that the Institutional Review Board is only responsible for ensuring the safety and integrity of human participants. I recognize that I am responsible for ensuring this research complies with the mission statement of the University.

The PI’s signature (and that of the faculty sponsor, if applicable) is required before this application can be processed (electronic signatures are acceptable). Send this application and all supporting documents to irb@caldwell.edu. Please note that this document and any others requiring IRB stamps must be in doc/docx format so that the electronic stamp may be applied. Any other formats will be returned.

 **Principal Investigator** **Date**

 **Faculty Sponsor Date**

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| **This Section is for IRB Use Only**[ ]  Approved [ ]  Revisions Needed [ ]  Not ApprovedNotes:      Reviewed by:      Stamp:   |