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POLICY ON THE USE OF HUMAN SUBJECTS

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I. STATEMENT OF PURPOSE

Complete Wellness Institute maintains an Institutional Review Board on the *Use of Human Subjects in Research* (hereafter referred to as the IRB) comprised of at least five members. The IRB members are selected both from within and from outside Complete Wellness, Incorporated, and from different disciplines, to provide a range of perspectives. All members of the IRB are aware of issues relating to individual civil liberties. Since the members of the IRB represent a range of backgrounds, the board is competent to review a variety of projects and ensure that the rights of research subjects are protected. The board reviews proposed projects in terms of this policy, which is based on the bylaws of the IRB and the guidelines on human protection put forth by the *Office of Human Research Protections* of the *Department of Health and Human Services* (45 C.F.R. 46 "Protection of Human Subjects") as well as in terms of applicable standards of professional conduct and practice, modern ethical principles, and the consensus of contemporary community standards.

In their evaluations, the members of the IRB shall attempt in all cases to assure that inherent and potential risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and/or humanity. It is the role of the Complete Wellness Institute Institutional Review Board to minimize inherent and potential risks to subjects as much as is feasible, regardless of projected benefits to individuals or to society.

II. MEMBERSHIP OF THE INSTITUTIONAL REVIEW BOARD

The IRB of Complete Wellness Institute shall have no less than five members, with varying backgrounds, to promote complete review of research activities commonly conducted by the Institute. The IRB shall be sufficiently qualified through the expertise and diversity of the members, including consideration of their race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its decisions in safeguarding the welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct. The IRB shall therefore include persons knowledgeable in these areas.

The IRB may not consist entirely of members of one profession or one gender. However, selection must be made on the basis of qualified expertise, not solely on the basis of gender. The members of the IRB must all complete the human subjects online training before reviewing proposals and within five years of their service on the IRB. They must submit a certificate attesting to their completion of the training to the IRB Chair. Electronic copies of Certificates of Completion shall be stored in a secure online location which shall be shared with all members of the IRB and all applicable investigators.

Each IRB member shall be compensated with a stipend of $200 per year.

III. DEFINITIONS

A. "Human subject" means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.

B. "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

C. "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

IV. GENERAL REVIEW PROCEDURES

All Institute research projects and activities that involve human subjects, and that meet the definition of research in the Code of Federal Regulations (45 CFR 46(d)), regardless of the risk foreseen, require review and approval by the IRB, prior to the initiation of the project or activity. IRB review is required for projects or activities involving human subjects that are conducted on the Institute premises or elsewhere by faculty or employees. Each project and activity involving human subjects will be referred to the IRB, following the procedures outlined below. In case of full reviews, the research proposal will be reviewed by the IRB within a month of when the application is received.

Except when a project is excluded or exempt from review or when an expedited review procedure is used (see Sections V, VI, and VII), the IRB shall review proposed research at convened meetings at which a quorum of the members is present, including at least one member whose primary concerns are in non-scientific areas. Decisions of the IRB are rendered by a majority of all members present. Where any questions of significance arise, Board members absent from a meeting are apprised and their views solicited so that participation to the fullest degree is possible. Minutes of each IRB meeting are circulated to all IRB members. Minutes shall be stored in a secure online location shared with all members of the IRB and all investigators involved and must be in PDF form.

No members of the IRB will be involved in the review of any project in which the member has a direct professional responsibility or some conflicting interest, except to provide information requested by the IRB.

The IRB may in its discretion consult with outside sources of expertise beyond or in addition to that available on the IRB. Such sources could include additional legal counsel or members of the Institutional Review Boards of other institutions. The outside sources may not vote on matters before the IRB. Each IRB member is encouraged to exercise independent judgment, so that reviews may be conducted in the most objective manner possible.

The IRB has the authority to make decisions involving projects or activities that involve human subjects including:

1. Determination of whether the project is exempt from IRB review;

2. Determination of whether the project is eligible for expedited review;

3. Determination of the level of risk to which human subjects may be exposed;

4. Approval of the project or activity and procedures as submitted;

5. Specification of modifications in the protocol necessary to obtain IRB approval;

6. Disapproval of the project or activity; or

7. Suspension or termination of IRB approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Application to the various categories of review shall be made on the IRB forms available online on the IRB website.

The IRB shall notify investigators in writing within two days of the meeting of its decision to approve or disapprove the research, or of modifications required to secure its approval. If the IRB decides to disapprove a research project or activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

All research projects and activities approved by the IRB shall be subject to continuing review at appropriate intervals. Research that is conducted, supported or otherwise subject to regulation by any federal department or agency shall be reviewed at least annually.

Researchers seeking approval for projects approved by other IRBs (that also adhere to the regulations set forth in 45 C.F.R. 46) must submit documentation of that IRB approval, along with whatever materials were originally submitted to that IRB (proposal, instruments, etc.), in electronic copy. The Complete Wellness Institute IRB Chair or designee may determine if these materials are sufficient for the IRB to give its approval (secondary concurrence), or if more information (e.g., a proposal on the appropriate IRB forms) is required, in which case the submission will be reviewed according to the procedures outlined below. If the project is approved based on the materials submitted to another IRB (and that IRB's approval), the Complete Wellness Institute IRB must be kept apprised of all continuing reviews and addenda submitted to the primary IRB (at the other institution), and may request further information to continue its approval at any time.

V. PROJECTS EXCLUDED FROM REVIEW (FOR WHICH NO SUBMISSION TO THE IRB IS NECESSARY)

Oral History projects are not required to be presented to the IRB in any form. As guided by statements of the Oral History Association, the Complete Wellness Institute IRB defines oral history as gathering, preserving, and interpreting the voices and memories of people and communities through recorded interviews with participants in past events and ways of life. It is the IRB's position that oral history projects do not constitute "research" as defined by the OHRP, as they are not intended to contribute to generalizable knowledge, but rather are intended to enhance understanding of historical periods, contexts, and events. Those using oral history must conform to the principles and practices for oral history developed by the Oral History Association.

VI. PROJECTS EXEMPT FROM REVIEW

Broad categories of research that do not use living human subjects or that normally present little or no risk of harm to subjects may be exempt from formal review by the Board. In these cases, researchers must submit an IRB-EXEMPT form to the IRB, so that the IRB Chair (or designee) may review the study and make the determination of whether or not the project is indeed exempt. In general most social, economic and educational research is exempt if the only involvement of human subjects is in one or more of the following categories:

1. The use of survey and interview procedures;

2. The observation of public behavior; or

3. The study of existing data, documents, records, or specimens.

Specifically, the following categories of research are exempt from review (based on 45 C.F.R. 46.101(b)):

1. Research undertaken without the intention of involving living human subjects.

2. Research in which the only involvement of human subjects will be in one or more of the following categories:

    a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

        (1) Research on regular and special education instructional strategies; or

        (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

    b. Research involving survey procedures, interview procedures, educational testing, or observation of public behavior unless:

(1) information obtained will be recorded in such a manner that the human subjects can be identified, either directly or through identifiers linked to the subjects, and

(2) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation (e.g. when the research deals with the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol).

c. Research involving survey procedures, interview procedures, educational testing, or observation of public behavior, and the human subjects are elected or appointed public officials or candidates for public office, or when federal statutes require without exception, maintenance of confidentiality of personally identifiable information, throughout the research and thereafter.

d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

An investigator who believes that their project qualifies for exemption must submit one electronic copy of the IRB-EXEMPT form to the IRB Chair, describing the project and explaining why the investigator believes the proposed project qualifies for exemption.

The Chair will notify the investigator within a month whether the proposed research qualifies for exemption. If the research does not qualify, the Chair will advise the investigator in writing concerning the submission of the appropriate forms for request for review. If the proposal qualifies, the Chair will notify the investigator and file the signed copy of the form.

VII. RESEARCH QUALIFYING FOR EXPEDITED REVIEW

Research activities qualify for expedited review if they involve no more than minimal risk, as defined in III.B above, AND are included in the categories suitable for expedited review as determined by the Department of Health and Human Services (DHHS), listed in B below. In addition, minor changes to a previously approved research protocol may be acceptable for expedited review during the period for which approval is authorized.

The following categories of research are currently determined to be eligible for expedited review, based on OHRP guidelines:

1. Clinical studies of drugs and medical devices, only when a) the research is on drugs for which an investigational new drug application is not required, or b) the research is 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;

2. Collections of blood samples by finger stick, heel stick, ear stick or venipuncture, under the conditions described by DHHS;

3. Prospective collection of biological specimens for research by noninvasive means (e.g. hair and nail clippings, teeth, saliva);

4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves (e.g. physical sensors, muscular strength testing);

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);

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

7. Research on individual or group characteristics or behavior (such as studies of perception, cognition, motivation, communication, social behavior), or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;

8. Continuing review of research previously approved by the convened IRB, where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research- related interventions and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis;

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight above do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified;

10. Investigators who believe that their projects qualify for expedited review must submit to the IRB Chair one electronic copy of the IRB- EXPEDITED form. The forms will be reviewed by the Chair or an IRB member designated by the Chair. At their discretion, the investigator may be required to discuss the project with the Chair or the designated member. A research activity may be disapproved only under the full review procedure (Section VIII below).

The Chair will notify the investigator within a month whether the proposed research qualifies for expedited review. If the proposal does not qualify, the Chair will advise the investigator in writing concerning the submission of the appropriate forms for request for full review. If the proposal qualifies and is approved, the Chair will notify the investigator

and file the signed copy of the form. The remaining members of the Board will be advised of research proposals that have been approved under the expedited procedure.

VIII. RESEARCH THAT REQUIRES FULL IRB REVIEW

All projects that are not subject to exemption or expedited review are subject to full IRB review. The investigator must submit one electronic copy of the IRB-FULL form and a copy of the project or activity proposal. In order to approve the project, the IRB must determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (a) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;

3. Selection of subjects is equitable, taking into account the purpose of the research and the setting in which the research will be conducted;

4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, according to the Guidelines for Consent in IX below, and will be appropriately documented. The prospective subject or representative must be given sufficient opportunity to consider whether or not to participate. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

5. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

In each case, the IRB requires that the research activity be performed by scientifically or otherwise qualified persons with adequate supervision by professional personnel and that the general procedures employed are legal and acceptable by both national and local standards of practice.

Investigators who believe that their projects qualify for Full Board review must submit to the IRB Chair one electronic copy of the IRB- FULL form. The Chair then assesses the completeness and compliance of the application with these regulations and policies. After this initial review, the forms may be returned to the investigator with a request for more details or suggestions for change. Upon acceptance by the Chair, the application

is put on the agenda for the next scheduled IRB meeting. In certain cases, the investigator may be requested to attend the meeting to clarify the proposal and to respond to questions by members of the IRB.

If the proposal is approved, the Chair will notify the investigator and the original IRB-FULL form will be signed by three members of the IRB. If the proposal is not approved, reasons for denial will be provided in writing to the researcher.

IX. REQUIREMENTS FOR CONSENT

The requirements for informed consent, or its waiver, alteration, or exception apply regardless of the type of review—expedited or full—utilized by the IRB.

The investigator must provide the Board with assurance that truly informed and free consent of subjects at risk will be obtained by methods that are adequate and appropriate, and that carry the least possibility of coercion, undue influence, omission, error, or misunderstanding. The informed consent procedure and documents employed for this purpose shall contain no exculpatory language through which the subject or the subject's legally authorized representative is made to waive or appear to waive any of his or her legal rights, or to release or appear to release the researcher, Complete Wellness Institute or any of its personnel from any liability for negligence.

In many cases, research may involve children, persons with restricted educational backgrounds, or persons for whom English is not their native tongue. Consent is not "informed" if the person concerned cannot understand the consent form. The language used in the consent form must be appropriate for the age, education and intellectual levels of the persons who are to be subjects.

To obtain informed consent, the investigator must provide prospective subjects with the following information:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental. NOTE: This statement may be provided to the subject following the research project in cases where the “deception” is a material part of the project.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

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

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

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

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Such injury may consist of physical, psychological, emotional, financial, or other harm.

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

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. A statement informing subjects of their right to withdraw any consent given and, at the point of withdrawal, to require that their own data, including records, be eliminated from use after withdrawal.

When appropriate, the investigator must also provide prospective subjects with one or more of the following:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The potential consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

7. Plans for protecting the confidentiality of personally identifiable information.

[NOTE: These requirements for informed consent are not intended to preempt any applicable federal, state, or local laws.]

In most cases, the investigator should document informed consent by use of a written document that incorporates appropriate parts of the above requirements. This document must be approved by the IRB. The form may be read to or read by subjects or their legally authorized representatives, and must be signed by the subject or the

representative. The person signing the form must be given a copy of it. Under certain limited circumstances (as defined in 45 CFR 46.117(c)) the IRB may waive the requirement for a signed consent form.

In some instances, the investigator may prepare a "short form" written consent document which states that all elements required above were read to the subject or to a legally authorized representative. Short form consent requires that:

1. there must be a witness to the oral presentation;

2. the IRB must approve a written summary of the oral statement;

3. the consent form will be signed by the subject or representative;

4. the witness will sign the short form and a copy of the summary;

5. the person obtaining consent will sign a copy of the summary; and

6. a copy of the short form and the summary will be given to the subject or representative.

In no case shall an investigator propose, or the IRB approve, an informed consent procedure in which any possible or potential risk is knowingly or purposely minimized, misrepresented, or otherwise distorted.

All approved consent procedures will be retained by the IRB Chair, and all signed consent forms will be retained by the principal researcher.

X. CONFIDENTIALITY

All personnel associated with each project or activity involving the use of human subjects will ensure that confidentiality will be maintained with respect to individuals in the collection, storage, security, use, and ultimate destruction of all primary data.

Measures taken to assure confidentiality should be described to the IRB in writing by the investigator in each case, regardless of risks to subjects involved or of consent procedures used.

Exceptions to the confidentiality of data associated with individual human subjects are made only when disclosure is required by statutory or judicial authority or when the subject has given prior written approval for disclosure.

General information such as descriptions of consent procedures and outcomes of the review process and minutes of IRB meetings shall be publicly available information on the IRB website.

XI. IRB RECORDS

The IRB shall prepare and retain documentation of its activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and investigators.

5. A list of IRB members, including name, earned degrees, representative capacity, indications of experience sufficient to describe anticipated contributions to IRB deliberations, and any employment or other relationship with the Institute.

6. Statements of significant new findings regarding risk factors for subjects that appear during the course of the research.

All such records and minutes shall be retained for at least three years after completion of the research, and the records shall be accessible for inspection and copying by authorized persons, including representatives of the Department of Health and Human Services, at a reasonable time, place and manner.

XII. RESEARCH UNDERTAKEN WITHOUT THE INTENTION OF INVOLVING HUMAN SUBJECTS

In the event research is undertaken without the intention of involving human subjects but it is later proposed to involve human subjects, the research shall first be reviewed and approved by the IRB according to these procedures, before any such involvement occurs.

XIII. PROPOSED CHANGES TO A PROJECT

In the event an investigator proposes to make changes to an IRB-approved research project or activity, the changes may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects. Investigators proposing changes should submit a detailed description in writing of any substantive changes to the project as well as those modifications that change the risk to the subject, referring specifically to appropriate sections of the Research Proposal submitted with the original IRB form. Such reviews by the IRB will be undertaken at the

closest scheduled meeting of the IRB.

XIV. PROCEDURE FOR REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS

In the event of any unanticipated problems or serious noncompliance with protocols that involve risks to human subjects or others, the investigator or research subject must promptly report the matter to the IRB Chair.

XV. CERTAIN CATEGORIES OF RESEARCH

In research involving prisoners, pregnant women, fetuses, neonates and children, the IRB will follow the guidelines established in the Code of Federal Regulations at 45 CFR 46, and any future amendments.

XVI. ADDITIONAL ISSUES TO BE TREATED ON A CASE-BY-CASE BASIS

A. Longitudinal Research

The IRB may request the investigator in any project or activity extending over a period of time exceeding one year to obtain consent from subjects on a yearly basis.

B. Concealment or Deception

1. The IRB recognizes that it may be impossible to study some psychological processes without withholding information about the true object of the study or deliberately misleading the subjects. However, for any research project or activity that involves the use of deception or concealment, the investigator must demonstrate to the satisfaction of the IRB that:

    a. the potential benefits of the experiment exceed the risks to the subjects of using deception or concealment;

    b. alternative procedures avoiding concealment or deception are not available; and

    c. the investigator has considered the effects on the subjects of the way that the withholding of information or deliberate deception will be received.

2. Normally, it is expected that those who have been subjects in a project involving concealment or deception be so informed at the completion of the subject's participation in the study. In studies where the subjects are aware that they have taken part in an investigation in which the data have been collected using concealment or deception, the IRB may require the investigator to:

a. provide the subjects with any necessary information to complete their understanding of the nature of the research; and

b. discuss with the subjects their experience of the research in order to monitor any unforeseen negative effects or misconceptions.

C. Observational Research

1. Studies based upon observation must respect the privacy and psychological well-being of the individuals studied. The IRB may require that those observed give their consent to being observed and be made aware that they may be observed by strangers (unless the research project entails deception or concealment as a material condition of the project, in which case the investigator is required to comply with the guidelines set forth in Section XVI.B).

2. Additionally, the IRB may require assurance that strong consideration is taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

XVII. AUDIO AND VIDEO RECORDING

Audio and video recording of human subjects is a form of research that does not protect the anonymity of the subject. Therefore, certain precautions must be taken whether or not the project is exempted from review under Section VI:

1. Subjects should be informed that they will be recorded by audio or video for research purposes only. That is, the investigator and/or department may not use these recordings for purposes other than those specified in the research project.

2. The recording must be stored in a password-protected folder on a password-protected computer.

   a. In some cases, the IRB may require encryption of the file, as a further protection.

   b. In some cases, the IRB may prohibit use of recording devices that are connected to the Internet (e.g., cell phones, laptops). Such recordings may not be stored on devices connected to the Internet until after the appropriate password-protection/ encryption has taken place.

3. Only the investigator and, where appropriate, the investigator's advisor(s) or supervisor(s) may listen to or view the recording.

4. The recording must be destroyed or erased as soon as possible (e.g., upon transcription), but in no case later than the completion of the project.