Community Healthcare System Central IRB
Checklist for Initial Review of Proposals

(Form date 7/2021)

Protocol:

Principle Investigator: CHS CIRB #:

Form to be completed on initial receipt of Protocol Submission Form by CHS CIRB Office.

SUBMISSION APPLICATION REVIEW:	YES	NO	N/A
Is the research activity FDA regulated?			
Does the proposed activity involve obtaining information about living individuals?			
Does the activity involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens?			
Does the proposed activity involve analysis of existing data and/or specimens? Existing specimens include those that are already in existence at the time of the proposed research and specimens that will be collected in the future for purposes other than the currently prosed research (i.e., ongoing collection of specimens for a tissue repository located within the CHS system?			
Is this human subject's research?			
QUALIFICATIONS OF THE INVESTIGATORS			
Is an Individual Investigator Agreement required for any investigator or key personnel?			
Have all investigators and key personnel completed required education?			
Have all sections of the submission form been addressed?			
CVs and privileges for all investigators attached?			
CVs and privileges for all research staff attached?			
Certification of Investigator Responsibilities signed?			
Current COI Disclosure Statement on file for all personnel?			
Is a Financial Disclosure Addendum required?			
Investigator's Brochure sent to Pharmacy for review?			
Do the Investigators have the appropriate academic and clinical credentials for this study?			
Does the Protocol require any additional privileges? If yes, has the investigator initiated a request to Medical Staff Services?			
Does the protocol require any of the clinical research staff or ancillary personnel to perform any procedure or treatment that requires additional credentialing or privileges?			
If the proposed investigator or any key personnel is a student or trainee within the system, has appropriate faculty or institutional support been guaranteed?			
INITIAL REVIEW OF CONSENT			
Were 2 copies of all consents included?			
Is the investigator requesting a waiver or alteration of consent?			
Is a Waiver of HIPPA Authorization required for the study?			
Is a translated copy of the consent included?			

	YES	NO	N/A
If Yes, is the Certification of the translator included?			
Is a Short Form consent included?			
Was the Community Healthcare System format used?			
Are the dates and version on consents consistent with those listed in the protocol?			
Are all pages numbered sequentially?			
Is the study title identical to that listed on the protocol?			
Is the name, address, and phone number of each investigator listed?			
Is the name and phone number of a person from the study office listed in case of emergencies?			
Is the source of financial support for the study listed?			
Is there a statement regarding the phone number and availability of the Human Protections Administrator?			
Signature/date line for subject			
Signature/date line for Legally Authorized Representative			
Line for LAR's authority to act for the subject			
Signature/date line for person explaining consent			
Signature/date line for witness, witness statement optional			
Statement and signature/date line for Investigator optional			
Language added: "A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site any time."			
GINA Language added: "The Genetic Information Nondiscrimination Act of 2008 is Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law: 1. It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information. 2. Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance. o This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.			
RESEARCH DESIGN AND METHODS			
Does the research design carry enough likelihood of yielding data sufficient to warrant the risks to the subjects?			
Does the research design carry enough likelihood of accruing a sufficient number of patients to warrant initiation at this site?			
Does the research design reflect current practice?			

	YES	NO	N/A
Is this protocol similar in design to currently approved protocols? If yes, should this protocol replace the current protocol?			
Are the study procedures and study visits clearly outlined and described?			
Does the study have a valid scientific design and yet pose an inappropriate risk for subjects? • Is there substantial evidence that one of the arms is inferior to another or to standard/conventional care or will deprive a subject of his right to receive a life-prolonging treatment? • Is it possible that one arm will expose a subject to a serious risk or harm?			
Are all procedures clearly defined as either research related or completed as part of the subject's clinical care (regardless of study participation)?			
Where appropriate, have alternative procedures that might be advantageous to the potential research subjects been described?			
For Placebo controlled studies wherein an effective treatment exists for the study disease/condition: 1. Has justification been provided for the placebo arm? 2. Does the consent form sufficiently inform the patient of the possibility of receiving a placebo and therefore "no treatment"?			
DATA COLLECTION, PRIVACY, CONFIDENTIALITY			
Are there defined plans for data and statistical analysis including the use of interim analysis, stopping rules and endpoints?			
Are there adequate study design safeguards in place (e.g., Data Safety Oversight Committee, interim data analysis?)			
Does the protocol outline specific steps that will be taken (i.e., during study participation, after study participation, and with the publication of study results) to ensure that the subject's participation in the research study and respective data will be confidential?			
Is a Data Use Agreement necessary? If yes, was it submitted to the IRB?			
Is a Material Transfer Agreement necessary? If yes, was it submitted to the IRB?			
HUMAN SUBJECTS			
Are inclusion and exclusion criteria clearly specified and appropriate?			
Does the study design include vulnerable subjects? If yes, did the investigator include the appropriate justification for the inclusion of these subjects?			
Does the study design specifically exclude a population of subjects for ethnic, cultural, or due to language barriers? If yes, did the investigator include the appropriate justification for the exclusion of these subjects?			

	YES	NO	N/A
RECRUITMENT PROCEDURES			
Are methods of subject recruitment legal, ethical and free from coercion or undue influence? Has cold-calling been avoided?			
Is the selection of subjects equitable? • Are these subjects appropriate for the protocol?			
Are there additional safeguards in place for subjects likely to be vulnerable to coercion or undue influence?			
Do the recruitment materials promise or imply a certainty of cure or other benefits beyond what is contained in the protocol and the informed consent?			
Do the recruitment materials claim, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device?			
Do the recruitment materials include the terms "new treatment", "new medication" or "new device"?			
Do the recruitment materials offer "free medical treatment" or emphasize that the subjects will be paid?			
Recruitment materials may include: 1. The name and address of the clinical investigator and/or research facility 2. the condition under study and/or the purpose of the research 3. in summary form, the criteria that will be used to determine eligibility for the study 4. a brief list of participation benefits, if any 5. the time or other commitment required of the subjects 6. the location of the research and the person or office to contact for further information.			
RISKS/BENEFIT RATIO: Consider only those risks and benefits that may result from the research as opposed to those that would result from standard therapies not involved in the research.			
Have appropriate statements regarding reproductive risks and birth control been included (if appropriate)?			
Are all the risks (including known incidence) clearly described?			
Have adequate safeguards been adopted to minimize risk exposure as much as possible?			
Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result?			
Are the potential benefits to the subject (if any) clearly described?			
COSTS AND PAYMENTS			
Are the financial obligations of the subject, the sponsor and the institution clearly described? Is the language included in this section the same as that included in the protocol?			
Is cost/availability of the experimental drug/device following			

study completion addressed?			
	YES	**NO**	**N/A**
Are any additional costs to the subject that may result from participation in the research clearly defined?			
Do any payments to subjects seem sufficient yet not large enough to demonstrate undue influence?			
Is there a clear description distinguishing between the costs related to research procedures versus clinical care procedures (done regardless of study participation)?			
A statement that the subject's biospecimens (even if identifiers are removed may be used for commercial profit and whether the subject will or will not share in this commercial profit.			
REVIEW OF CONSENT FORM			
Is the language clear, concise, non-technical language used throughout?			
VOLUNTARY CONSENT			
Is there a statement that the subject's 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 subjects is otherwise entitled?			
Is there an offer by the investigator(s) to answer questions?			
STUDY DESCRIPTION			
Is there a clear statement of the purpose of the study?			
Is there a clear explanation of the reason a particular subject was invited to participate?			
Is there a clear statement that the subject is participating in a research study?			
Is the approximate number of subjects to be studied noted?			
Is the duration and length of each subject's participation included?			
Are all procedures described clearly defined as either research related or completed as part of the subject's clinical care (regardless of study participation)?			
Is the dose, route, and frequency of drug(s) to be given noted?			
Is the FDA approval status of the drugs/device indicated?			
If the study involves the use of questionnaires, is there a description of the general content and time required to complete them?			
Is the total volume of blood to be drawn described in tablespoons or teaspoons or ounces?			
Are biospecimens being collected and stored? If yes, is it specified where the samples are stored, how they are identified, how long they will be stored, and who will have access to the samples?			
For research involving biospecimens, is there a statement as to whether the research will or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen?			

	YES	NO	N/A
RISKS/BENEFITS SECTION			
Is there a complete and clear description of any foreseeable risks or discomforts to the subject (i.e., is quantitative information on the expected frequency of the listed side effects provided)?			
Are reproductive risks adequately described and is appropriate birth control language included?			
A statement that a 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.			
Are the potential benefits that may be reasonably be expected from the research (if any) clearly described? If there are no direct benefits to the subject, is this clearly stated?			
ALTERNATIVE TREATMENTS			
If applicable, have all alternative procedures or courses of treatment, if any, that might be advantageous to the subject been satisfactorily described?			
NEW INFORMATION			
Is there a statement regarding new information that might influence a subject's decision to participate or remain enrolled in the study?			
A statement regarding whether clinically relevant research results, including individual research results, be made available to the subject?			
CONFIDENTIALITY			
One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens; 1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or 2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.			
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what circumstances.			
HIPAA AUTHORIZATION			
If the following information has not addressed in the body of the investigational consent in the section that explains HIPAA Authorization or Confidentiality, the CHS CIRB approved HIPAA Authorization form must be added to the consent.			

	YES	NO	N/A
Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy?			
A description of the information to be used or disclosed			
The name or specific identification of the person(s) or class of persons authorized to release the information			
A description of each purpose of the requested use or disclosure.			
Does the section sufficiently state who will have access to the subject records (e.g., the FDA, study sponsor, CHS study staff, CHS CIRB)? Does it give a number for the CHS IRB?			
An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study", "none", or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including the creation and maintenance of a research database or research repository.			
Signature and address of the individual and date			
A statement telling the subject of their right to revoke their authorization at any time.			
A statement telling the subject that we cannot condition treatment on their agreement to sign the authorization. However if they do not agree to sign, they cannot be enrolled in the research study.			
A statement telling the subject that if we disclose their information based on their signed authorization that there is a potential for that information to be re-disclosed by the recipient whose actions may not be regulated by HIPAA.			
The authorization must be in plain language.			
RIGHT TO WITHDRAW			
Is this section clearly worded and non-coercive?			
Are the risks of subject's withdrawal clearly stated?			
Are reasons why a subject might be withdrawn from the study by the investigator/sponsor without regard to the subjects' or the legally authorized representative's consent clearly defined?			
Are procedures for ensuring continued care of the withdrawn subject adequately addressed?			
COMPENSATION FOR INJURY			
Is the issue of compensation to the subject for research related injury available and whom to contact in the event of an injury?			

Statement of Reviewer: *Must provide explanation for all denials*

- ☐ Does not require CHS CIRB review
- ☐ Proceed to Exempt Review
- ☐ Proceed to Expedited Review
- ☐ Proceed to Full Board Review
- ☐ Accept Facilitated Review
- ☐ Return to PI for more information
- ☐ Deny Facilitated Review
- ☐ Deny Further Review

Comments:

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Signature of Reviewer/Date Signature of Reviewer/Date