



CPHS OVERVIEW

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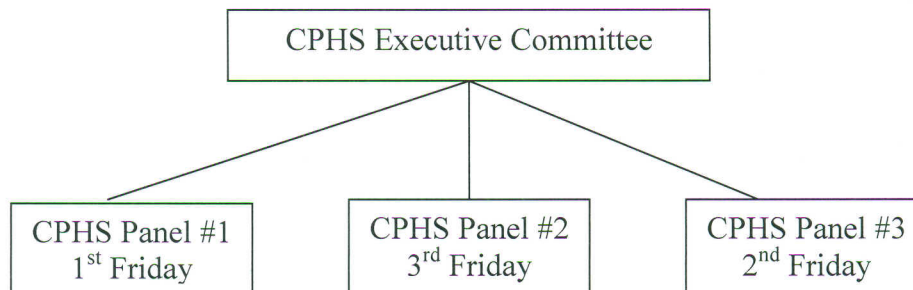
Human Subject: Individual from which an investigator conducting research obtains data through intervention/interaction or private information from some other source.

Basic Ethical Principles: 1) Respect for persons, 2) Beneficence, and 3) Justice

Basic Reviewing Objectives: 1) Risks are minimized, 2) Risks are reasonable vs. benefits, 3) selection is equitable, 4) informed consent is obtained, 5) subject data and safety is protected, 6) confidentiality maintained, and 7) additional safeguards provided for vulnerable populations.

CPHS Jurisdiction: Research being conducted by an employee of the university or at any one of the university's facilities (including collaborating facilities such as Memorial Hermann Hospital System and HCPC).

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Submissions that Require CPHS Review: 1) Initial Reviews, 2) Change Requests, 3) Continuing Reviews, 4) Protocol Deviations, 5) Data and Safety Monitoring Reports, 6) Adverse Events, 7) Miscellaneous Submissions, and 8) Study Closures.

CPHS Additional items of consideration:

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- **Protocols can qualify for Exempt, Expedited, or Full Committee Review**
- **Human Subjects Education is needed for all study personnel**
- **Department Chair signoff is required for Initial and Continuing Reviews**
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IRB New Protocol Submission Details:

Full title of your study:

List Departments associated with this study:

Assign key study personnel (KSP) access to the study (investigator, co-investigators, study coordinators, etc.).

Provide Study Personnel Contact Information

Please list the names and credentials and ROLES for all Principal Investigators and Co-Investigators on this study. (Examples include John Smith, PhD - Statistician; Mary Jones, MD - Surgeon; Jane Doe, MD - Patient Recruitment)

Identify the locations where this study will be conducted:

Identify the funding source for this protocol and indicate the status of the funding (pending, approved, in negotiations, etc):

Has this study undergone scientific peer-review by one of the following institutions or agencies: M. D. Anderson Cancer Center, National Institutes of Health (NIH), Center for Disease Control (CDC), Department of Defense (DOD), National Institute of Justice (NIJ) or American Heart Association (AHA)?

Research Summary (500 words or less - The summary required for this section of the application should include the following information. Please note that this summary must be in lay language, as this summary is reviewed by all members of the CPHS, including our non-technical/non-medical members. Summaries not provided in lay language will be sent back for revision, which may possibly result in a delay of the protocol's review).

- **Purpose**
- **Procedures**
- **Course of Study**

Please designate if any vulnerable populations will be included in the study (i.e. children, pregnant women, physically or mentally disabled, economically or educational disadvantaged, prisoners, etc).

Provide the study Inclusion criteria:

Provide the study Exclusion criteria:

Is any racial/ethnic group excluded?

Provide justification for inclusion or exclusion of any group (gender, race, or other):

Will drugs be used in this study?

If YES, is this study being conducted under an approved IND?

Provide details regarding the all study drugs being used within this study:
Will medical devices be used in this study?

If using a DEVICE, is this study being conducted under an approved IDE or HDE?

Provide details regarding the all study devices being used within this study:

Indicate the Study Type (i.e. intervention, pilot, etiology, prospective, descriptive, etc):

Describe experience of subjects while participating in this research.

Specify which procedures and/or diagnostic tests are considered routine clinical care.

Specify which procedures and/or diagnostic tests are being performed for research purposes only.

Specify which of the research procedures and/or diagnostic tests are being performed solely to screen for study eligibility.

Will interviews, questionnaires, and/or surveys be part of the study?

Describe method of data analysis:

Summarize procedures to protect the confidentiality and anonymity of subjects:

Describe the plan for monitoring data and safety.

Describe the possible risks to participants (including psychological harm, economic harm, social stigmatization, legal harm, and physical harm if applicable). Include justification of those known risks.

Describe ways in which this risk, if any, will be minimized.

Identify the potential benefits of this study?

Does the PI or sponsor have a DSMB in place or planned for this trial (Explain)?

How will subjects be recruited into this study?

Who will do the recruiting?

Are you screening or recruiting from or through the patient base of a healthcare provider?

Describe the process of obtaining subjects' consent (Include where it will take place, who will obtain the consent and how cultural issues will be addressed, etc.)

Will non-English speaking people be approached to participate in this study?

Will a translation be available for non-English speaking subjects?

If the study involves minors, describe the process of obtaining parental permission and how the assent of the minor will be sought.

In case of injury, please explain who will pay for the treatment.

Will subjects receive any compensation for participation in this study?

Describe compensation and/or remuneration being offered to subjects. Provide amount and justification.

Will there be any costs to subjects associated with their participation in research?

Will Specimens be obtained specifically for this study?

Will you be accessing Protected Health Information (PHI - any identifiable health information) from a covered entity?

Is the use or disclosure being sought solely for research on the PHI of those who are deceased?

Is this a retrospective chart review?

Is the information you are obtaining solely to prepare a research protocol?



CPHS SUBCOMMITTEE REVIEW FORM

Protocol #: HSC- ___ - ___ - ___

Brief Synopsis of Study: (Include 1-2 sentence BRIEF description of study design, target audience, intervention, and outcome measures. Do not include inclusion and exclusion criteria, measurement instruments, enrollment procedures that do not need to be mentioned here but may be mentioned below if substantive concern exists).

CPHS Staff: (check any of the following issues that may be passed directly to CPHS staff):

- minor grammatical errors (for instance in the consent form)
- editorial issues (such as consistency with first or third person)
- administrative issues (such as lack of signatures, missing IND number, etc.)

Substantive Subcommittee Concerns: (List key substantive subcommittee concerns with the protocol including unreasonable risk to subjects; issues of equity, justice, beneficence, or other ethical issues; unreasonable exclusions such as language or pregnancy): _____

Subcommittee Member Recommendation: (Subcommittees should generally come prepared with a specific motion in mind, recognizing that full committee discussion may warrant changes):

- Approve
- Approve Pending: explanation of _____
- Approve Pending: changes in _____
- Defer
- Reject

	Yes	No	N/A
Does the research involve <u>children and greater than minimal risk?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Does the research present the prospect of direct benefit to the child?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Is it only a minor increase over minimal risk and will it give vitally important knowledge about the disorder?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Does it present opportunity to understand, alleviate, or prevent a serious problem affecting children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continuing Review Frequency:

- 12 months
- 6 months
- Other

Issue(s) that warrant full committee discussion:

Scientific Issues

Please respond to the following questions (Lay Reviewers: Answer only those questions in areas in which you feel qualified):

- Yes No Is there a clearly formulated hypothesis?
- Yes No Is the experimental design (i.e., randomization; placebo controls; phase I, II, or III) appropriate to test the hypothesis?
- Yes No Are the significance/relevance and wider implications of the proposal appropriate?
- Yes No Are the data to be obtained adequate to draw significant conclusions?
- Yes No If applicable, is the statistical analysis of the data sufficient?

- Yes No Has the investigator considered negative/not informative results; and, in light of these, has he/she proposed alternative approaches for testing the main hypothesis?
- Yes No Are eligibility and exclusionary criteria appropriate, clearly defined and detailed?
- Yes No Are exclusions adequately justified?
- Yes No Are the follow-up procedures sufficient?
- Yes No Are there adequate subject numbers to answer study questions?

Are the following descriptions adequate:

- Yes No Study procedures, with enough detail to determine what each subject group is being asked to do?
- Yes No Screening
- Yes No Follow-up
- Yes No Does the research preclude or delay standard of care?

Risk/Benefit Assessment

Risk:

Regulatory definition of minimal risk: 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 encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 (h)(i)).

Check the appropriate risk category:

1. Yes No **Is there adequate information to evaluate possible risks and benefits of the research?**
2. The research involves **more** than minimal risk to subjects.
 - a. The risk(s) represents a **minor** increase over minimal risk, or
 - b. The risk(s) represents **more than** a minor increase over minimal risk.
 - i. Does the scientific merit outweigh the risks? **Yes** **No**
 - ii. Are benefits maximized and risks minimized? **Yes** **No**
 - iii. Is it of "indeterminate risk" **Yes** **No**

(e.g., Phase I, II, or III vaccine or IDE/IND trial)
3. Are the risks adequately identified, evaluated, and clearly described? **Yes** **No**
4. Is the risk/benefit ratio acceptable for proceeding with the research? **Yes** **No**
5. Yes No **Are psychological, social, economic and/or legal risk addressed?**

6. Yes No **Is risk to others (i.e., risks related to disclosure of genetic information) addressed?**

Benefit

Potential benefits can apply directly to the subject (health-related, emotional or psychosocial) or may contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is **NOT** considered to be a benefit, but rather compensation for research-related inconveniences.

Is the potential benefit stated clearly and appropriately? Yes No

Check the appropriate benefit category:

The research involves **no prospect of direct benefit** to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

The research involves **prospect of direct benefit** to individual subjects.

General Protocol Review (check all that apply):

	YES	NO	N/A
Do the investigators have the knowledge/skills required to conduct the procedures in the protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the proposal involve special concerns ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Vulnerable potential research volunteers? (children, fetuses, prisoners, mentally ill) 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Influence or possible coercion that unduly entices consent 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Sensitive information (child abuse, violence, STDs, illegal substance abuse) 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Screening or diagnosis of diseases with significant potential for loss of insurance or other services, stigmatization, or self-stigmatization 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Genetic research 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Research using blood and other body tissues 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Deception, either deliberate or implied 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Radiation or biohazardous material or chemical exposure 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are procedures adequate for confidentiality/anonymity/security ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Will data be coded? Held in a secure manner? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Do the procedures sufficiently protect against the risks of loss of confidentiality?
 - Is the data/specimens stored without identifiers?
- Is a waiver or alteration of consent requested or appropriate?
- Are procedures adequate for obtaining **informed consent**?
- Is the consent form included?
- Is verbal or implied consent appropriate (if applicable)?
- Does the consent list any alternative procedures, if any, that might be advantageous to subjects?
- Does the consent clearly outline the subject's participation and duration in study?
- Does the consent clearly outline what procedures are experimental and what is standard treatment?
- Are other relevant documents included? (parental permission form, assent form, telephone script, etc.)
- Is there assent? If a waiver is requested, is it justified?
- Is there parental permission? If a waiver is requested, is it justified?
- Does the protocol adequately:
- describe the process of consent?
 - {properly informing prospective volunteers with skilled personnel obtaining consent, unhurried time, proper setting}
 - Assess prospective volunteers' comprehension?
 - Assess prospective volunteers' autonomy?
 - Describe documenting the consent process?
 - Is the timing of consent appropriate to the situation?
 - Does the approach protect the privacy of potential subjects and families?
 - Does the approach protect families from coercion or undue influence?
 - If the researcher is known to families/subjects,

is there potential for undue influence because of the relationship?

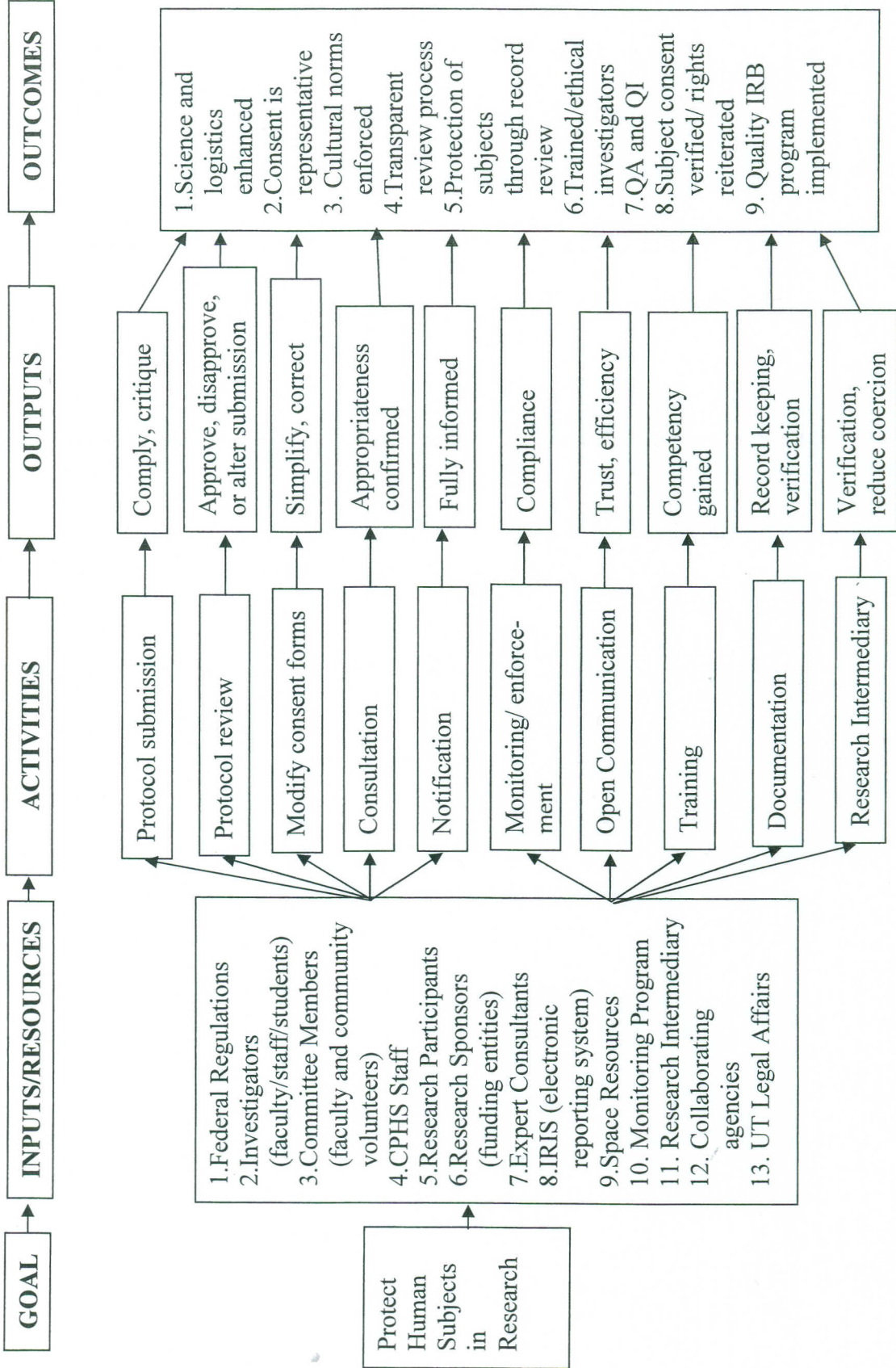
- Are subject paid for participating? Could the payment be coercive for the targeted population?
- Are there any additional costs for which subject will be responsible?
- Consequences of a subject's decision to withdraw (safety issues)
- Build procedures for monitoring safety, if necessary?
- Have procedures for the equitable selection and participation of potential subjects?

Has the investigators included a Conflict of Interest form?

If there is a grant application or industry protocol for this study, does the Human Subjects Application and consent correspond to the grant application/protocol?

Are there sufficient resources to protect human subjects?

- Personnel – e.g. number and expertise
- Services (medical, social, psychological)
- Monitoring
- Ancillary care
- Equipment
- Communication resources (e.g. translation)
- Other:





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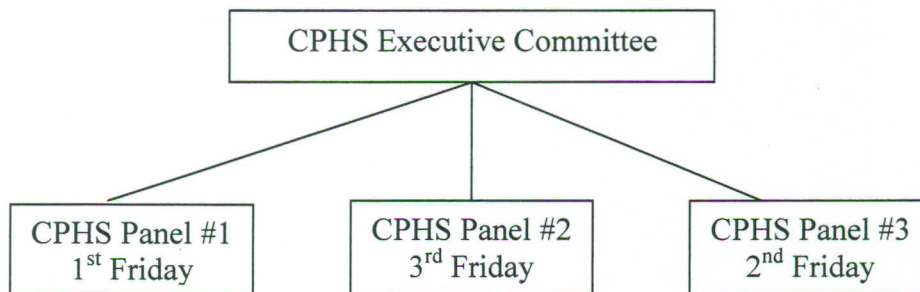
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