

## Worksheets for IRB Primary Reviewers

### Instructions:

These worksheets are intended as guides for primary reviewers. The first is a recommended sheet for the primary reviewer to use in order to focus the discussion during committee meetings; the second is a worksheet with suggested questions for primary reviewers.

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CHS #

Principal Investigator

(Sub investigators and/or staff)

Title of Study

Sponsoring Agency

Single or Multiple Sites

Enrollment (# of subjects/enrolment goal)

Project Start Date

New Study

Renewal Status

Brief Description of Study (Try to describe “arms” if appropriate)

Brief outline of the theory behind the study, if possible

Brief background material (other studies, available data, etc.)

Evaluate protocol – if any problems, bring them out

Address: Respect for Persons

Beneficence

Justice

Always weigh: Risks vs. Benefits

Review the Informed Consent – is it simple, clear, inclusive?

Are burdened individuals / vulnerable populations involved?

Recommendations

Approve

Approve with Stipulations (reviewed by Chair)

Defer (bring back to the Committee)

Please utilize and complete all the sections of this worksheet pertinent to the research proposal. This can also serve as the basis for your presentation to the Committee. Please comment on each of the pertinent sections, in the order presented, during your presentation to the Committee.

**I. Social and Scientific Value**

1. Does the research evaluate a diagnostic or therapeutic intervention that could reasonably lead to improvements in health or well-being?  
Yes[  ]                      No[  ]                      N/A[  ]
  
2. Do you perceive any significant or irremediable impediment to the practical/clinical implementation of the diagnostic/therapeutic intervention under evaluation?  
Yes[  ]                      No[  ]                      N/A[  ]
  
3. Is the research a preliminary etiological, pathophysiological, or epidemiological study to develop such an intervention?  
Yes[  ]                      No[  ]                      N/A[  ]
  
4. Does the research test an hypothesis that can generate important knowledge about the structure or function of human biological systems, even if the knowledge is not of immediate practical usefulness?  
Yes[  ]                      No[  ]                      N/A[  ]
  
5. Is the research question clinically relevant, considering the existent standard diagnostic or therapeutic interventions available for the condition under evaluation?  
Yes[  ]                      No[  ]                      N/A[  ]
  
6. Are you aware of any impediment to the public dissemination of the research results, whether the latter are positive or negative?  
Yes[  ]                      No[  ]                      N/A[  ]

Comments and Suggestions Referenced to Sections Above:

## II. Scientific Validity and Conduct of the Study

### A. General Considerations

1. Does the proposal have (an) unambiguous scientific objective(s), with valid end-points (clinical or surrogate) proposed for measurement?  
Yes[  ]                      No[  ]
2. Does the proposal have a methodologically and statistically valid study design?  
Yes[  ]                      No[  ]
3. Is it a reasonable expectations that the number of eligible subjects needed for the study will be available for enrollment, and within a reasonable timeframe?  
Yes[  ]                      No[  ]
4. Do the enumerated investigators have the necessary qualifications and expertise to conduct the research competently and safely?  
Yes[  ]                      No[  ]
5. Are appropriate facilities and equipment present to conduct research of this kind?  
Yes[  ]                      No[  ]

### B. Study-Specific Considerations

1. Is the proposed research relevant when considering the established efficacy of existent diagnostic or therapeutic interventions available for the condition in question?  
Yes[  ]                      No[  ]
2. For phase III trials, is a genuine null hypothesis (clinical equipoise) present?  
Yes[  ]                      No[  ]                      N/A[  ]
3. For phase III randomized trials using an active, comparator, is a clinically relevant comparator of proven efficacy being used, and is the dose and mechanism of its administration appropriate?  
Yes[  ]                      No[  ]                      N/A[  ]

Comments and Suggestions Referenced to Sections Above:

### III. Fair Subject Selection

1. Are the subjects being recruited adequately representative of the population in which the diagnostic or therapeutic intervention is intended for use? (Justified generalization of results)  
Yes[  ]                      No[  ]
  
2. Are subjects being recruited form a particular group of individuals on the basis of situational expediency alone?  
Yes[  ]                      No[  ]
  
3. Do the recruitment procedures specifically target persons in particular socioeconomic, racial or gender classes?  
Yes[  ]                      No[  ]  
If yes, is this justified by the research objective(s)?  
Yes[  ]                      No[  ]
  
4. Are members of vulnerable groups (e.g. persons with limited or impaired decisional capacity; prisoners; children) being systematically recruited?  
Yes[  ]                      No[  ]  
If yes, is this justified by the research objective(s)?  
Yes[  ]                      No[  ]
  
5. Are there recruitment/exclusion criteria that inappropriately exclude specific classes of individuals?  
Yes[  ]                      No[  ]
  
6. Groups and individuals bearing risks and burdens derivative of research participation should *not* be systematically excluded (e.g. on socioeconomic or political grounds) from experiencing its potential benefits. Is this requirement met for this research?  
Yes[  ]                      No[  ]
  
7. Are persons eligible for recruitment, but at a substantial risk for harm derivative of specific and identifiable personal characteristics, excluded from participation?  
Yes[  ]                      No[  ]

Comments and Suggestions Referenced to Sections Above:

#### IV. Favorable Risk : Benefit Ratio

Research may involve components in the control and/or experimental arms that offer the prospect of direct benefit to subjects, and/or components that are designed *solely* to answer the research question (enable the generation of generalizable knowledge). Risks associated with these components should be assessed separately.

1. For components that offer the prospect of direct benefit to subjects, are the risks reasonable (and minimized) in relation to the purported benefits?

Yes[  ]                      No[  ]

2. For components designed *solely* to answer the research question, are risks reasonable (and minimized) in relation to (i) the ability of the research to generate generalizable knowledge, and (ii) the potential benefits of such knowledge?

Yes[  ]                      No[  ]

3. Justification of placebo controls in phase III trials:

First requirement: A placebo may be justified when one or more of the following pertain (check applicable):

[  ] i. There is no standard treatment.

[  ] ii. Standard therapy has been shown to be no better than placebo.

[  ] iii. Evidence has arisen creating substantial doubt regarding the net therapeutic advantage of standard therapy.

[  ] iv. Use in a population of patients who are refractory to standard treatment and for whom no standard second-line treatment exists.

[  ] v. Testing add-on treatment to standard therapy when all subjects in the trial receive all treatments that would normally be prescribed.

[  ] vi. Patients have provided an informed refusal of standard therapy for minor condition for which patients commonly refuse treatment and when withholding such therapy will not lead to undue suffering of the possibility of irreversible harm of an magnitude.

Second Requirement: Subjects are fully informed (Consent Document) about any therapy that will be withdrawn or withheld for purposes of (a) the research, (b) the anticipated consequences of the withdrawing or withholding of the therapy, and (c) the reasons why investigators deem a placebo-controlled trial to be necessary.

Are the preceding requirements met?

Yes[  ]                      No[  ]

4. Research using medical records and/or genetic research:

Do the research procedures adequately protect the subject's informational privacy and confidentiality interests?

Yes[  ]                      No[  ]                      N/A[  ]

Comments and Suggestions Referenced to Sections Above:

**V. Evaluation of Consent Process and Document**

1. Is the process by which consent is acquired, as described in the Application and Protocol, appropriate?  
Yes[  ]                      No[  ]                      ]
  
2. If individuals without, or with potentially impaired decisional capacity are potential subjects, are adequate protections in place?  
Yes[  ]                      No[  ]                      N/A[  ]
  
3. Are you generally satisfied that the document will be comprehensible to the potential subject(s)?  
Yes[  ]                      No[  ]
  
5. If the research involves children, is there a suitable assent document which will be comprehensible to the potential subject(s)?  
Yes[  ]                      No[  ]                      N/A[  ]
  
6. Does the submitted document contain any exculpatory language that may be construed as requiring the subject to waive any legal rights as a condition of participation (e.g. securing compensation for research-related injury; rights derivative of ownership interests in cells/tissue, etc.)?  
Yes[  ]                      No[  ]                      N/A[  ]

Comments and Suggestions Referenced to Sections Above:

**VI. Additional Considerations and Comments**

1. Do you believe the possible risks to subjects are such that an independent Data and Safety Monitory Board or Audit schedule should be constituted?

Yes[ ] No[ ] N/A[ ]

2. Is an annual review of this research adequate to monitor the safety of the research subjects?

Yes[ ] No[ ]

3. If subjects are compensated for participation, do you have any concern about inappropriate inducement?

Yes[ ] No[ ] N/A[ ]

General Comments and Suggestions About the Protocol:

General Comments and Suggestions about the Completed Application for Research Form:

Name of Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_