UK Healthcare Risk Management Committee

NON-INDEMNIFIED CLINICAL PROJECT
RISK ASSESSMENT EVALUATION

I. ADMINISTRATIVE:

Title of Study:	

Study Principal Investigator:	
Study PI Department:	
Room:	
Study PI Phone:	
Study PI Fax:	
Study PI e-mail:	
Name(s) of co-PIs, if any:	
Additional Contact:	
IRB #:	

Research Attributes

Please select if any of the following are applicable:

- ☐ Cancer Patients (Markey Cancer Center Studies)
- ☐ Using CCTS Services (CRU inpatient/outpatient, regulatory, etc.)
- ☐ All Others (Neither of the above)

Which type of IRB review is applicable to the research?

UK IRB: ☐ Full ☐ Expedited ☐ Exempt

NOTE: Expedited or Exempt reviewed studies do not require non-indemnification review

IRB Review Completed By:

☐ UK IRB

☐ NCI Central IRB

☐ Other Central IRB (List): _____

Sponsorship/Funding

☐ Commercially-sponsored study (i.e. pharmaceutical, industry) with limited or no indemnification in contract

☐ Investigator-Initiated clinical trial (i.e. internally funded)

☐ CCTS Pilot

☐ NIH, Cooperative Group study, or other governmental investigator initiated clinical trial (i.e. NIH, VA, NCI, NSF, etc.)

Investigational drug /device involved

Is there an investigational drug, device or therapeutic approach involved that is <u>not</u> FDA approved?

yes ◯ no ◉

If yes, provide IND/IDE number and sponsor; or documentation of FDA exemption from requirement to file IND.

IND/IDE# _____

Name of individual/sponsor holding IND/IDE: _____

II. SCIENCE SECTION

1. Study Rationale, including study purpose and objectives (1-2 Paragraphs):

2. Study design including the proposed schema planned randomization, stratifications, sample size estimates and planned end points:

3. Indicate the risk associated with the study as described below. This should match the Risk Level as described in the IRB Application.

◉ **A. Research not involving greater than minimal risk.**

Definition: 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.

○ **B. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.**

Definition: More than minimal risk to the subject is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if:

(a) the risk is justified by the anticipated benefit to the subjects; and

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Please estimate level of risk:

☐ Moderate Risk = 1

☐ High Risk = 2

○ **C. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.**

Definition: More than minimal risk to the subject is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if:

(a) the risk represents an increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and

© the intervention or procedure is likely to yield generalizable knowledge about the subje'ts' disorder or condition which is of vital importance for the understanding or amelioration of the subje'ts' disorder or condition.

Does the benefit expected to be gained from the study outweigh the risks associated with it?

☐ Yes ☐ No

PLEASE RETAIN THIS FORM FOR YOUR RECORDS.

THIS SECTION TO BE COMPLETED BY NON-INDEMNIFICATION COMMITTEE

Risk Assessor's Comments:

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☐ Recommend expedited review

☐ Recommend full review

Primary Reviewer

or MCC Committee Chair _____ **Date** _____

mm/dd/yyyy

Committee Chair _____ **Date** _____

mm/dd/yyyy

Determination: **Date of Determination:** _____

☐ Approved

☐ Approved pending revisions

☐ Not Approved

PLEASE RETAIN THIS FORM FOR YOUR RECORDS.