Clinical Study PI Questionnaire

The rights of sponsors to inventions arising from clinical studies performed at the University can be the subject of challenging negotiations. The University’s negotiating position is defined by policy guidelines, which include consideration of the University’s Principal Investigator’s:

* degree of involvement in the conception and intellectual development of the clinical study protocol; and
* interest in benefiting from possible commercial exploitation of inventions arising from the study that are unanticipated new uses or modifications of the study drug or device.

Your answers to the following questions will help the University’s contracting officials negotiate the appropriate disposition of intellectual property rights.

TO BE COMPLETED BY THE PRINCIPAL INVESTIGATOR

PROJECT TITLE:

PI NAME:

SPONSOR: SPONSOR PROTOCOL NO.:

1. IT IS MY UNDERSTANDING THAT THE SUBJECT STUDY IS:

[ ]  a FDA-regulated preclinical or animal study

[ ]  a FDA-regulated human-subject clinical drug study – Phase (if known)

[ ]  a FDA-regulated human-subject clinical device study

[ ]  NOT an FDA-regulated study

[ ]  Do not know

1. PLEASE DESCRIBE YOUR DEGREE OF INVOLVEMENT IN THE CONCEPTION AND/OR YOUR INTELLECTUAL CONTRIBUTION TO THE DEVELOPMENT OF THE STUDY PROTOCOL:

[ ]  None

[ ]  Not significant

[ ]  Significant – Please describe:

**The University typically attempts to negotiate rights in inventions such that research sponsors have a first right to negotiate a license to commercialize inventions arising from that research. The University and its inventors could potentially receive financial consideration from any commercial exploitation of such inventions. However, clinical study sponsors occasionally insist on royalty-free rights to commercialize, or full ownership of inventions arising from such clinical studies. Under those circumstances, the University and its inventors would receive no financial consideration from commercial exploitation of such inventions.**

1. PLEASE INDICATE BELOW THE CIRCUMSTANCES UNDER WHICH YOU WOULD BE WILLING TO PARTICIPATE IN THE SUBJECT STUDY:

[ ]  I would not participate in this clinical study unless the University secured rights to financial consideration from study inventions in which University inventors made an inventive contribution.

[ ]  The University should seek to secure rights to financial consideration from study inventions in which University inventors made an inventive contribution, but I would still participate in the study if the University did not succeed in obtaining such rights.

[ ]  I feel that the University should NOT seek to secure any financial consideration from the study inventions for which University inventors made an inventive contribution.

[ ]  I have no opinion on this matter.

[ ]  COMMENTS:

**Investigator Signature:** **Date**: