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	MA-OI-09	Investigator Led Study Form Letter	4

77 4th Avenue

Waltham, MA 02451, USA

Email: researchstudies_idx@revvity.com

Dear Clinical Affairs,

We would like to submit an investigator initiated clinical study to Revvity for consideration of support.

The clinical study, _____, investigates the _____. Our hypothesis is _____.

The study will include _____ patients (see accompanying protocol for details) and require approximately _____ time to complete. To support the study we are requesting _____, such as service, kits, personnel, overhead to be provided by Revvity. We will provide Revvity with the clinical data for review, which includes data analysis, preparation of abstracts, presentations and publications.

Sincerely,

INVESTIGATOR NAME:

INSTITUTE:

INSTITUTE ADDRESS:

Complete form on next page

Investigator Led Study Proposal

Please complete all required fields. Forms with missing information will be returned to the submitter for completion. If a field cannot be completed, please specify the reason within that field.

Proposed Study

Title:

Request Date:

Principal Investigator Contact Information

Name:

Title:

Address 1

Address 2

US ONLY: City, ST, Zip

Outside US: Postal Code, City, Country

Phone/Fax:

E-mail:

Institution Contact Information

Name:

Address 1

Address 2

US ONLY: City, ST, Zip

Outside US: Postal Code, City, Country

Phone/Fax:

E-mail:

Study Information

Background and Rationale

Provide background and rationale that the study is attempting to answer (do not exceed one page)

Hypothesis

List the clinical hypotheses in order of priority:

Objectives

Study Design/Clinical Plan

Summarize your study design and methodology, including key elements such as: study type, sample size, endpoints, subject criteria, procedures, potential adverse effects, etc.

Statistical Plans

Include justification for clinical sample size and primary hypothesis testing:

Timelines and Study Plans

Number of Sites:

Site Names:

Number of Subjects:

IRB Meeting Date:

Budget Summary

Total Requested:
(specify currency and
include overhead)

In-kind Support:	T-SPOT™.TB	Yes	No
	T-SPOT™.CMV	Yes	No
	T-Cell Select™	Yes	No
	Leucosep™ Tubes	Yes	No
	AIM-V™ Medium	Yes	No
	T-SPOT™.Flex (RUO)	Yes	No
	RPMI Medium (Life Tech.)	Yes	No
	D-PBS (Life Tech.)	Yes	No

Personnel:

Overhead:

Other:

Additional sources of funding required?
(Yes/No) If Yes, please be specific.

Publication Plan

Are you planning to present your data at a scientific meeting?

Where are you planning to submit for publication? (journals, etc.) Please also indicate publication type (abstract, manuscript etc.):

Please list your target date for submission of publication.

Is a third party involved and if so, who?:

Please submit both the cover letter and study protocol to Revvity Clinical Affairs at researchstudies_idx@revvity.com