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	Document Title	Document Description	Version No.
	<b>MA-OI-09</b>	<b>Investigator Led Study Form Letter</b>	<b>2</b>

Oxford Immunotec Ltd, a Revvity company  
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 OX14 4SE

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**Dear Clinical Affairs,**

We would like to submit an investigator initiated clinical study to Oxford Immunotec 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 Oxford Immunotec. We will provide Oxford Immunotec with the clinical data and involve Oxford Immunotec in the data analysis and dissemination of the data in the form of abstracts, presentations and publications.

Sincerely,

INVESTIGATOR NAME:

INSTITUTE:

INSTITUTE ADDRESS:

*Complete form on next page*

# Investigator Led Study Proposal

All fields are required. An incomplete form will be returned to the submitter. If a field is not completed, please note the reason.

## 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 on unanswered question(s)  
the study is attempting to answer (do not exceed one page)

### Hypothesis

List the clinical hypotheses in order of priority:

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Objectives

**Study Design/ Clinical Plan**

Provide the experimental design, inclusion/exclusion criteria, 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
	DPBS?	Yes	No
	RPMI?	Yes	No
	AIM-V?	Yes	No
	Leucosep tubes	Yes	No
	T-Cell <i>Xtend</i>	Yes	No
	T-Cell <i>Select</i>	Yes	No
	Other:		

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 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 IDx Clinical Affairs at [researchstudies\\_idx@revvity.com](mailto:researchstudies_idx@revvity.com)