University of Michigan Office of Research & Sponsored Projects

Standard Operating Procedures & Policies

Category:	Miscellaneous
Policy No.:	900.02
Title:	Human Research Contracts Checklist

I. Purpose & Overview

To outline the process by which ORSP ensures that externally-funded human research contracts comply with external and internal policies.

II. Procedure / Policy

ORSP will also ensure the following elements are addressed in each written sponsored research agreement
(which may include the applicable Protocol incorporated into the agreement by reference) involving
numan subjects:

	subjects:
	Medical care for participants with a research-related injury, where appropriate
	Sponsor's duty to report findings that could affect the safety of participants or influence the conduct of the study, where applicable, in studies where Sponsors conduct site visits or site monitoring
	Sponsor's duty to report and monitor data and safety reports, where applicable, in studies where Sponsor is responsible for conducting data and safety monitoring
	Plans for disseminating research findings and publication or disclosure of results, where applicable
	Sponsor's ongoing duty to notify the University of results which could directly affect patient safety after the study ends, where applicable
Fre	equently Asked Questions
ap	plicable.

III.

Not

IV. Resources

http://orsp.umich.edu/

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Page - 1 -	Last Revised Date: 02/01/11
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