

**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 human 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

III. Frequently Asked Questions

Not applicable.

IV. Resources

<http://orsp.umich.edu/>

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Approved by: Elaine Brock, Senior Associate Director	Last Revised By: A. Coulter