

UW HUMAN SUBJECTS ASSISTANCE PROGRAM (HSAP)



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Research Portfolio

- University – 3 campuses (Seattle, Tacoma, Bothell)
 - 3 hospitals (UW Medical Ctr., Harborview, Northwest)
- International
- \$1.67 billion in sponsored grants & contracts (FY22)
- 6100 open-active protocols
 - 400 Clinical Trials (7%)
 - 230 Greater than minimal risk (4%)
- 17% UW studies reviewed by external IRB



Human Subjects Assistance Program

- What is it?

- *The University of Washington (UW) respects and values the volunteer human subjects who participate in UW research and recognizes that subjects may assume some risk by participating in research. The Human Subjects Assistance Program (HSAP) is a discretionary program that may provide limited medical and other assistance to subjects who experience a research-related medical problem that is more likely than not caused by UW-conducted research.*

Available Assistance

- Waiver of charges for injury-related treatment at a UW Facility for up to \$250,000
- Reimbursement for out-of-pocket expenses or for healthcare not provided by an authorized UW facility up to \$10,000
- Provide for additional expenses or assistance as agreed to by the study participant and the UW Office of Clinical Risk Management



What's not covered

- Lost wages, lost time, or pain and suffering
- Expenses covered by the National Vaccine Injury Compensation Program
- Expenses that are covered by the federal Public Readiness and Emergency Preparedness Act
- Expenses that are covered by a national health service or national health insurance in a country other than the United States

HSAP Applicability

- Applicability of the program is based on the 'event' not the study or its location
- Event must be a qualifying medical problem:
 - Physical or psychological disorder diagnosed by licensed healthcare practitioner
 - Occurred during course of UW-conducted research
 - More likely than not was directly caused by the research intervention, treatment, item, design or procedures
 - There is a recognized treatment for it
 - One year or less has elapsed between the likely cause of the medical problem and discovery
- Event is part of human subjects research for which the UW is 'engaged'

Not applicable



- Medical problems due to:
 - Normal course of disease or underlying medical condition
 - Usual and ordinary patient care (i.e., standard treatment for individual's disease or condition)
 - Substantial or deliberate noncompliance on the part of the study participant with the research procedures or instructions
- Problems associated with study procedures not under UW direct control (e.g., work subcontracted to another entity)
- Industry-funded and initiated research

Program Management

- Oversight and management of the program is a shared responsibility primarily between HSD and the UW Office of Clinical Risk Management

HSD	Clinical Risk Management
Assess study for potential eligibility (i.e., study involves potential medical risks associated with interventions)	Make final determination of eligibility
Ensure HSAP language part of informed consent	Administer program benefits (e.g., \$10k reimbursement, medical bill write-off)
Intake of reported events (by participants or researchers)	
Assess for qualifying medical event	
Report to Clinical Risk Management	

Program History

- 1972-79 Human Subjects Compensation Plan
 - Commercially insured, worker's compensation model
 - 17 claims paid: \$16,164
 - Insurance premiums: \$262,500
- 1979 Folded into self-insured general liability program
 - Funded by UW central administration
 - Pay up to \$10k/person for reimbursement of out-of-pocket expenses for research related injury
- Over time, component writing off bills for care received at UW Medicine included
 - Cap of \$250k and 1 year reporting limitation added
 - Definition of 'qualifying medical problem' expanded

Challenges

- **Access**
 - Burden on researchers and/or study participants to report
- **Coverage boundaries**
 - Increased collaborations with research partners (Who's responsible?)
 - Determining causality of the problem (Is it research-related?)
- **Funding**
 - Relies on UW & UW Medicine support
 - Low usage (What if claims significantly increased?)

