Federal Consent Elements for IRB Approval

Federal regulations specify basic and additional elements for the informed consent document. The IRB's requests for changes should be clearly related to addressing these elements, UW template information, or institutional policy. The full text of the federal consent elements can be found on page 15 of the regulatory text (see 45CFR46.116. b and c): HHS Regulations on Human Subjects Research

Basic Consent Elements		Applicable sections of the UW Consent to Participate in Research Template

An explanation of the design of the study and what the participants are being asked to do.		• Key information section
		• Why are the researchers doing this study?
		• What will I need to do in this study?
		  ○ What is being tested?
		  ○ Does it involve randomization?
		  ○ How long will I be in the study?
		• Detailed Information:
		  ○ If I take part in the study, what will I do?
		  ○ Optional study activities

Information about study risks		• Key information section: What are some reasons I might not want to be in this study? • What are the study risks? • For DoD personnel: any risk to fitness for duty or loss of access/duty
Description of potential benefits		• Key information section: What are some reasons I might want to be in this study? • Will being in this study help me in any way?
Any alternatives to the research		• Key information section: Do I have to be in the study? • Your choices may include • Can I be removed from the research without my agreement?
Privacy and confidentiality protections		• What happens to the information collected for research? • Protected health information (PHI) used in this study; release of information • Certificate of Confidentiality • Limits on confidentiality (if you or others are at risk of harm) • Sharing with sponsors, monitors/auditors, regulatory agencies, collaborators, services • Prisoners' medical records • What will happen to my [data/biospecimens/data and biospecimens] after my participation ends?
Compensation and coverage for injury		• Will it cost anything to be in the study?

		• Will I receive anything for participation? • Industry sponsor compensation policy • What happens if I am injured or get sick because of this study? • COVID-19 disclosure and Countermeasures Injury Compensation Program • DoD payments to participate
Whom to contact		• Researcher information directly under the Title • Who can I talk to about this study? • Questions, concerns, complaints, or think participation has hurt you
A statement that participation is voluntary		• Key information: Do I have to be in the study? • What happens if I say yes, but I change my mind later? • Consent signature block • Prisoner participation will not increase benefits in housing/correctional assignments, or date of parole/release
Statements about how data and specimens may be used in the future		• What happens to the information collected for research?: Use of research information and biospecimens in future research • Optional study activities
Additional elements of informed consent		
Difference between research and health care		• How is research different from health care?
Genetic testing or other genomic analysis disclosure		• If I take part in the study, what will I do? • Information about genetic research
Audio or video recordings or photographs		• If I take part in the study, what will I do?
Note about unforeseeable risks and pregnancy risks		• What are the possible risks or discomforts?
Information about stopping the study by the treatment team		• Can I be removed from the research without my agreement?
Any additional costs		• Charging for health care services you would ordinarily be responsible to pay • Released prisoners disclaimer to obtain insurance or Medicaid coverage

Steps to withdraw from the study		• What happens if I say yes, but I change my mind later?
		  ○ Contact the researcher
		  ○ Data retention/removal
		  ○ Taking back HIPAA authorization

A new findings/new information statement		• What happens if I say yes, but I change my mind later?
The number of subjects being studied		• How many people will be in this study?

Clarifying that profits may accrue from the use of information and/or biospecimens		• Will I receive anything for participation?
Plans to return clinically relevant research results		• Will I receive the results of research tests?
Creation (or not) of a medical record		• Will information from this study go in my medical record?
Posting on ClinicalTrials.gov		• Required disclosure of a description of the trial and summary results
Communication with study team		• Permission to communicate about the study by email
Funding and financial interests		• Who is funding this study? • Financial interest disclosure