

INFORMED CONSENT DOCUMENT CHECKLIST

Institutional Review Board and Human Subjects Office

The **Informed Consent Document (ICD) template** includes all of the [elements of consent](#) required by the [Federal Regulations](#) to ensure appropriate consent for research subjects.

The purpose of this checklist is to:

- Facilitate consistency between the Informed Consent Document and the eResearch (HawkIRB) application
- Assist researchers when submitting new applications and modifications to existing applications
- Assist HSO reviewers, compliance staff, IRB Chairs and IRB members when reviewing new studies, modifications, and studies chosen for monitoring

The following tables include the consent headings and references to applicable sections of the HawkIRB application:

- **Informed Consent Document – General**
 - Includes template sections that are in the majority of ICDs
- **Informed Consent Document – Study Specific**
 - Includes template sections that are unique to certain types of studies

Elements of Consent Key

*	Basic Elements of Informed Consent (45 CFR § 46.116.b)
**	Additional Elements of Informed Consent (45 CFR § 46.116.c)
***	University of Iowa Policies
****	Other

HawkIRB Key

Section #	Section Content
I.	Project Introduction
II.	Research Team
III.	Funding/Other Support
IV.	Project type
V.	<u>Other Committee Review</u>
VI.	Research Subjects
VII.A	Location & UI Role
VII.B	Intervention & Washout
VII.C	Genetic Testing
VII.D	Recruitment/Screening/Consent/Enrollment
VII.E	Randomization/Procedures/Compensation
VIII.	Risks
IX.	Benefits
X.	Privacy & Confidentiality
XI.	Data Analysis
XII.	Future Research
ROC	Record of Consent

Informed Consent Document – General

Consent Heading	Element N/A	Applicable HawkIRB Section
PI Name & Research Contact Information *		<input type="checkbox"/> II.1 <input type="checkbox"/> II.5
Title & Purpose of Study *		<input type="checkbox"/> I.2 <input type="checkbox"/> I.4
How Many People Will Participate**		<input type="checkbox"/> VI.1 <input type="checkbox"/> VI.6
How Long Will I Be in the Study *		<input type="checkbox"/> VII.E.6
What Will Happen During This Study *		<input type="checkbox"/> I.4 <input type="checkbox"/> VII.E.6-8 Check ICD for all that are applicable <input type="checkbox"/> V.1-8 – drug <input type="checkbox"/> V.3 – contrast <input type="checkbox"/> V.9-19 – radiation <input type="checkbox"/> V.20 – recombinant DNA\RNA <input type="checkbox"/> V.23 – VA Consent (only for IRB-03) <input type="checkbox"/> VII.B.2 <input type="checkbox"/> VIII.C.1 <input type="checkbox"/> VII.D.26 <input type="checkbox"/> VII.D.37-45 <input type="checkbox"/> VII.E.2
SSN Usage ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.19 <input type="checkbox"/> X.2
Data/specimen sharing*	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.B.1 (Registry, Repository, possibly Clinical Trial) <input type="checkbox"/> VII.C.7 <input type="checkbox"/> X.4 <input type="checkbox"/> X.6 <input type="checkbox"/> XII.4
Audio/Video Recording/Photographs***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.5 <input type="checkbox"/> VII.E.6
What are the Risks of this Study*		<input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
What are the Benefits of this Study*		<input type="checkbox"/> IX.1 <input type="checkbox"/> IX.2
What Other Treatments are There**	<input type="checkbox"/> N/A	<input type="checkbox"/> IV.1 (Regular Review in compliance with ICH-GCP) <input type="checkbox"/> VII.B.1 (clinical trial) (required if both responses are selected)
Will it Cost Me Anything to be in this Study**		No corresponding HawkIRB section
Will I be Paid for Participating*	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.9-19

Do the Researchers Have Financial Interest in Study***	<input type="checkbox"/> N/A	<input type="checkbox"/> III.3
Who is Funding this Study***	<input type="checkbox"/> N/A	<input type="checkbox"/> III.1
What if I am Injured as a Result of this Study*		No corresponding HawkIRB section
Will You Keep My Name on File to Give to Others *	<input type="checkbox"/> N/A	<input type="checkbox"/> X.6 <input type="checkbox"/> XII
What about Confidentiality *		<input type="checkbox"/> VII.C.6 <input type="checkbox"/> X
Will My Health Information be Used During this Study****	<input type="checkbox"/> N/A	<input type="checkbox"/> V.21 <input type="checkbox"/> V.25 <input type="checkbox"/> VII.A.1 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> ROC.1
Report unexpected findings from research testing ** (conducted with clinical quality procedures)	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1
Is Being in this Study Voluntary*		<input type="checkbox"/> VII.D.29
• What if I Decide to Drop Out of Study*		<input type="checkbox"/> VII.E.6
• Will I Receive New Info about Study while Participating**		<input type="checkbox"/> Protocol
• Can Someone Else End my Participation in this Study**		<input type="checkbox"/> III.1 (sponsor) <input type="checkbox"/> VI.13 <input type="checkbox"/> VIII.1 (i.e. if you become pregnant is exclusion criteria or study intervention poses a risk to a fetus) <input type="checkbox"/> Protocol (sponsor may stop participation)
What if I Have Questions *		<input type="checkbox"/> II.5 <input type="checkbox"/> ROC.4
Optional Agreements ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.B.1 (Registry, Repository, possibly Clinical Trial) <input type="checkbox"/> VII.C.9 <input type="checkbox"/> VII.E.5 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> XII.4

Informed Consent Document – Study Specific

Consent Heading	Element N/A	Applicable HawkIRB Section
Registry/Repository *	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.B.1 <input type="checkbox"/> XII.2 <input type="checkbox"/> XII.4
Genetic Research **	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.C.1
GINA **	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.C.1
ROC ***	<input type="checkbox"/> N/A	<input type="checkbox"/> V.21 <input type="checkbox"/> V.25.a <input type="checkbox"/> VII.A.1 <input type="checkbox"/> ROC.1 (does meet)
Randomization process/Randomized Clinical Trial *	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.2 <input type="checkbox"/> VII.E.6
Pregnancy Testing for minors ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.6 <input type="checkbox"/> VI.13 <input type="checkbox"/> VII.D.26 <input type="checkbox"/> VII.E.6
MRIs and Imaging Scans ***	<input type="checkbox"/> N/A	<input type="checkbox"/> V.9-16 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
GWAS **	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.C.8 <input type="checkbox"/> X.6
Placebo *	<input type="checkbox"/> N/A	<input type="checkbox"/> V.1.a <input type="checkbox"/> VII.B.6
Women capable of becoming pregnant during study **	<input type="checkbox"/> N/A	<input type="checkbox"/> V.9-16 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
Testing for Reportable Diseases ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.13 <input type="checkbox"/> Protocol
Radiation ***	<input type="checkbox"/> N/A	<input type="checkbox"/> V.9-16 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
Certificate of Confidentiality ****	<input type="checkbox"/> N/A	<input type="checkbox"/> X.7 <input type="checkbox"/> III.1 (NIH funded) <input type="checkbox"/> VII.1 <input type="checkbox"/> VII.2
Studies Focusing on Violence, Abuse, Self- Injury **	<input type="checkbox"/> N/A	<input type="checkbox"/> I.4 <input type="checkbox"/> I.5 <input type="checkbox"/> VII.E.4 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
Signature Boxes		
Minor & parent ****	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.6 <input type="checkbox"/> VII.D.30
Legally Authorized Representative *	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.28 <input type="checkbox"/> VI.32 <input type="checkbox"/> VII.D.29
Person Who Obtained Consent signature**** •if by mail or email	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.D.29 <input type="checkbox"/> VII.D.30



Translated ICD – Non English version****	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.16	<input type="checkbox"/> VII.D.29	<input type="checkbox"/> VII.D.30
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