

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. It is not intended for research that qualifies under an Exemption category ([§45 CFR 46.104](#)).

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 Section Key

I.	Project Introduction
II.	Research Team
sIRB	Single IRB Sites
III.	Funding/Other Support
IV.	Project Type
V.	Other Committee Review
VI.	Subjects
VII.A.	Location and UI Role
VII.B.	Intervention & Washout
VII.C.	Genetic Testing
VII.D.	Recruitment/Screening/Consent
VII.E.	Randomization/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 *		☐ II.1 ☐ II.5
Title & Purpose of Study *		☐ I.2 ☐ I.4
How Many People Will Participate**		☐ VI.1 ☐ VI.6
How Long Will I Be in the Study *		☐ VII.E.6 – Study procedures
What Will Happen During This Study *		☐ I.4 ☐ VII.E.6-8 – Study procedures, recontact, compensation <u>Check ICD for all that are applicable</u> ☐ V.1-8 – Drug ☐ V.3 – Contrast ☐ V.9-19 – Radiation ☐ V.20 – Recombinant DNA/RNA ☐ V.23 – VA Consent (only for IRB-03) ☐ VII.B.2 – Drug washout ☐ VII.C.1 ☐ VII.D.35-44 – Deception & debriefing ☐ VII.E.1&2 – Randomization ☐ VII.E.5
SSN Usage ***	☐ N/A	☐ VII.E.9 – Compensation ☐ X.2
Data/specimen sharing*	☐ N/A	☐ I.6 – Registry, Repository, possibly Clinical Trial ☐ VII.C.7 ☐ X.4 -6 ☐ XII.1-5
Audio/Video Recording/Photographs***	☐ N/A	☐ VII.E.4 ☐ VII.E.6
What are the Risks of this Study*		☐ VIII.1 ☐ VIII.2
What are the Benefits of this Study*		☐ IX.1 ☐ IX.2
What Other Treatments are There**	☐ N/A	☐ I.5 – Regular Review in compliance with ICH-GCP ☐ I.6 – Clinical trial Required if both responses are selected
Will it Cost Me Anything to be in this Study**		☐ VII.E.11
Will I be Paid for Participating*	☐ N/A	☐ VII.E.9-11 – Compensation plan, attach Cash Handling Plan, if needed

Do the Researchers Have Financial Interest in Study***	☐ N/A	☐ III.3 ☐ III.5
Who is Funding this Study***	☐ N/A	☐ 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 *	☐ N/A	☐ X.5-6 ☐ XII.1 ☐ XII.4
What about Confidentiality *		☐ VII.C.6 ☐ X.4 ☐ XII
Will My Health Information be Used During this Study****	☐ N/A	☐ V.21 ☐ V.25 ☐ VII.A.1 ☐ VII.E.6 – Project procedures ☐ ROC.1
Report unexpected findings from research testing ** (conducted with clinical quality procedures)	☐ N/A	☐ VII.E.6 – Project procedures ☐ VIII.1
Is Being in this Study Voluntary*		☐ VII D.16 ☐ VII.D.27
• What if I Decide to Drop Out of Study*		☐ VII.E.7
• Will I Receive New Info about Study while Participating**		☐ Protocol
• Can Someone Else End my Participation in this Study**		☐ III.1 – Sponsor ☐ VI.13 ☐ VII.B.8 ☐ VIII.1 (i.e. if becoming pregnant is an exclusion criteria or if study intervention poses a risk to a fetus) ☐ Protocol – Sponsor may stop participation
What if I Have Questions *		☐ II.5 ☐ ROC.4
Optional Agreements ***	☐ N/A	☐ I.6 – Registry, Repository, possibly Clinical Trial ☐ VII.C.9 – DNA test results ☐ VII.E.4 – Audio/video/photo ☐ VII.E.6 – Study procedures ☐ XII.4

Informed Consent Document – Study Specific

Consent Heading	Element N/A	Applicable HawkIRB Section
Registry/Repository *	☐ N/A	☐ I.6 ☐ XII.2 ☐ XII.4
Genetic Research **	☐ N/A	☐ VII.C.1
GINA **	☐ N/A	☐ VII.C.1
ROC ***	☐ N/A	☐ V.21 ☐ V.25.a ☐ VII.A.1 ☐ ROC.1 – Does meet
Randomization process/Randomized Clinical Trial *	☐ N/A	☐ VII.E.2 ☐ VII.E.6
Pregnancy Testing for minors ***	☐ N/A	☐ VI.6 ☐ VI.13 ☐ VII.E.5 ☐ VII.E.6
MRIs and Imaging Scans ***	☐ N/A	☐ V.9-16 ☐ VII.E.6 ☐ VIII.1 ☐ VIII.2
GWAS **	☐ N/A	☐ VII.C.8 ☐ X.6
Placebo *	☐ N/A	☐ V.1.a ☐ VII.B.6
Women capable of becoming pregnant during study **	☐ N/A	☐ V.9-16 ☐ VIII.1 ☐ VIII.2
Testing for Reportable Diseases ***	☐ N/A	☐ VI.13 ☐ Protocol
Radiation ***	☐ N/A	☐ V.9-16 ☐ VII.E.6 ☐ VIII.1 ☐ VIII.2
Certificate of Confidentiality ****	☐ N/A	☐ III.1 – NIH funded ☐ VIII.1 ☐ VIII.2 ☐ X.7
Studies Focusing on Violence, Abuse, Self- Injury **	☐ N/A	☐ I.4 ☐ I.14 ☐ VII.E.4 ☐ VII.E.6 ☐ VIII.1 ☐ VIII.2
Signature Boxes		
Minor & parent ****	☐ N/A	☐ VI.6 ☐ VII.D.27
Legally Authorized Representative *	☐ N/A	☐ VI.28 ☐ VI.32 ☐ VII.D.28
Person Who Obtained Consent signature**** •if by mail or email	☐ N/A	☐ VII.D.12 ☐ VII.D.16
Translated ICD – Non English version****	☐ N/A	☐ VI.16 ☐ VII.D.28

Appendix

Developing Family Educational Rights and Privacy Act (FERPA) Compliant Informed Consent Documents

Informed consent

If an informed consent template is used, it may need to be modified to include:

- The records to be disclosed
- The purpose of the disclosure
- The specific party(ies) to whom the disclosure is to be made (cannot say 'research team member(s),' 'PI,' etc.)
- A dated student signature
 - Electronic signatures are permitted if the signature page is located on a HawkID required authentication website

Exempt Information Sheet

If an informed consent template is used, it may need to be modified to include:

- The records to be disclosed
- The purpose of the disclosure
- The specific party(ies) to whom the disclosure is to be made (cannot say 'research team member(s),' 'PI,' etc.)
- A dated student signature
 - Electronic signatures are permitted if the signature page is located on a HawkID required authentication website
- An attestation/consent acknowledgement statement
- A checkbox or other mechanism for acknowledging agreement

Consent and Web-based Platforms

- Survey must begin with informed consent/exempt information sheet with all required elements
- Must be clear that submitting the consent document will enroll participants and records will be used as described
- Authenticated HawkID login can be considered a valid e-signature and date

For more information about FERPA requirements, please see the [Research Involving Student Records](#) educational tool, available on the [Educational Tools](#) page of the [HSO website](#).