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.	Other Committee Review
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 *		☐ **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**
What Will Happen During This Study *		☐ **I.4** ☐ **VII.E.6-8** **Check ICD for all that are applicable** ☐ **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** ☐ **VIII.C.1** ☐ **VII.D.26** ☐ **VII.D.37-45** ☐ **VII.E.2**
SSN Usage ***	☐ **N/A**	☐ **VII.E.19** ☐ **X.2**
Data/specimen sharing*	☐ **N/A**	☐ **VII.B.1** (Registry, Repository, possibly Clinical Trial) ☐ **VII.C.7** ☐ **X.4** ☐ **X.6** ☐ **XII.4**
Audio/Video Recording/Photographs***	☐ **N/A**	☐ **VII.E.5** ☐ **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**	☐ **IV.1 (Regular Review in compliance with ICH-GCP)** ☐ **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*	☐ **N/A**	☐ **VII.E.9-19**

Do the Researchers Have Financial Interest in Study* **	☐ **N/A**	☐ **III.3**
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.6** ☐ **XII**
What about Confidentiality *		☐ **VII.C.6** ☐ **X**
Will My Health Information be Used During this Study** **	☐ **N/A**	☐ **V.21** ☐ **V.25** ☐ **VII.A.1** ☐**VII.E.6** ☐ **ROC.1**
Report unexpected findings from research testing ** (conducted with clinical quality procedures)	☐ **N/A**	☐ **VII.E.6** ☐ **VIII.1**
Is Being in this Study Voluntary*		☐ **VII.D.29**
• **What if I Decide to Drop Out of Study***		☐ **VII.E.6**
• **Will I Receive New Info about Study while Participating****		☐ **Protocol**
• **Can Someone Else End my Participation in this Study****		☐ **III.1** (sponsor) ☐ **VI.13** ☐ **VIII.1** **(i.e.** if you become pregnant is exclusion criteria **or** 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**	☐ **VII.B.1** (Registry, Repository, possibly Clinical Trial) ☐ **VII.C.9** ☐ **VII.E.5** ☐ **VII.E.6** ☐ **XII.4**

Informed Consent Document – Study Specific

Consent Heading	Element N/A	Applicable HawkIRB Section
Registry/Repository *	☐ N/A	☐ VII.B.1 ☐ 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.D.26 ☐ 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	☐ X.7 ☐ III.1 (NIH funded) ☐ VII.1 ☐ VII.2
Studies Focusing on Violence, Abuse, Self- Injury **	☐ N/A	☐ I.4 ☐ I.5 ☐ VII.E.4 ☐ VII.E.6 ☐ VIII.1 ☐ VIII.2
Signature Boxes Minor & parent **** Legally Authorized Representative * Person Who Obtained Consent signature**** ●if by mail or email	 ☐ N/A ☐ N/A ☐ N/A	 ☐ VI.6 ☐ VII.D.30 ☐ VI.28 ☐ VI.32 ☐ VII.D.29 ☐ VII.D.29 ☐ VII.D.30

Translated ICD – Non English version****	☐ **N/A**	☐ **VI.16** ☐ **VII.D.29** ☐ **VII.D.30**