# 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**<br>**Check ICD for all that are applicable**<br>☐ **V.1-8 –** drug ☐ **V.3 –** contrast ☐ **V.9-19 –** radiation<br>☐ **V.20 –** recombinant DNA\RNA<br>☐ **V.23** – VA Consent (only for IRB-03) ☐ **VII.B.2** ☐ **VIII.C.1**<br>☐ **VII.D.26** ☐ **VII.D.37-45** ☐ **VII.E.2** |
| | | |
| **SSN Usage ***** | ☐ **N/A** | ☐ **VII.E.19** ☐ **X.2** |
| | | |
| **Data/specimen sharing*** | ☐ **N/A** | ☐ **I.6** (Registry, Repository, possibly Clinical Trial)<br>☐ **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** | ☐ **I.5 (Regular Review in compliance with ICH-GCP)**<br>☐ **I.6 (clinical trial)**<br>**(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)<br>☐ **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)<br>☐ **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 | ☐ 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.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.14 ☐ VII.E.4 ☐ VII.E.6 ☐ VIII.1 ☐ VIII.2 |
| | | |
| Signature Boxes<br>Minor & parent ****<br>Legally Authorized Representative *<br>Person Who Obtained Consent signature****<br>●if by mail or email | <br>☐ N/A<br>☐ N/A<br>☐ N/A | <br>☐ VI.6 ☐ VII.D.30<br>☐ VI.28 ☐ VI.32 ☐ VII.D.29<br>☐ VII.D.29 ☐ VII.D.30 |

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

# 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.