

# 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**

|      |  |
|------|--|
| *    | <b>Basic Elements of Informed Consent</b> (45 CFR 46.116.b)      |
| **   | <b>Additional Elements of Informed Consent</b> (45 CFR 46.116.c) |
| ***  | <b>University of Iowa Policies</b>                               |
| **** | <b>Other</b>   |

**HawkIRB Section Key**

|        |                                      |
|--------|--------------------------------------|
| I.     | <b>Project Introduction</b>          |
| II.    | <b>Research Team</b>                 |
| sIRB   | <b>Single IRB Sites</b>              |
| III.   | <b>Funding/Other Support</b>         |
| IV.    | <b>Project Type</b>                  |
| V.     | <b>Other Committee Review</b>        |
| VI.    | <b>Subjects</b>                      |
| VII.A. | <b>Location and UI Role</b>          |
| VII.B. | <b>Intervention &amp; Washout</b>    |
| VII.C. | <b>Genetic Testing</b>               |
| VII.D. | <b>Recruitment/Screening/Consent</b> |
| VII.E. | <b>Randomization/Compensation</b>    |
| VIII.  | <b>Risks</b>                         |
| IX.    | <b>Benefits</b>                      |
| X.     | <b>Privacy &amp; Confidentiality</b> |
| XI.    | <b>Data Analysis</b>                 |
| XII.   | <b>Future Research</b>               |
| ROC.   | <b>Record of Consent</b>             |

## 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 – Study procedures  |
| What Will Happen During This Study *           |                              | <input type="checkbox"/> I.4 <input type="checkbox"/> VII.E.6-8 – Study procedures, recontact, compensation<br><b>Check ICD for all that are applicable</b><br><input type="checkbox"/> V.1-8 – Drug <input type="checkbox"/> V.3 – Contrast <input type="checkbox"/> V.9-19 – Radiation<br><input type="checkbox"/> V.20 – Recombinant DNA/RNA<br><input type="checkbox"/> V.23 – VA Consent (only for IRB-03) <input type="checkbox"/> VII.B.2 – Drug washout <input type="checkbox"/> VII.C.1<br><input type="checkbox"/> VII.D.35-44 – Deception & debriefing<br><input type="checkbox"/> VII.E.1&2 – Randomization <input type="checkbox"/> VII.E.5 |
| SSN Usage ***                                  | <input type="checkbox"/> N/A | <input type="checkbox"/> VII.E.9 – Compensation <input type="checkbox"/> X.2   |
| Data/specimen sharing*                         | <input type="checkbox"/> N/A | <input type="checkbox"/> I.6 – Registry, Repository, possibly Clinical Trial<br><input type="checkbox"/> VII.C.7 <input type="checkbox"/> X.4 -6 <input type="checkbox"/> XII.1-5  |
| Audio/Video Recording/Photographs***           | <input type="checkbox"/> N/A | <input type="checkbox"/> VII.E.4 <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"/> I.5 – Regular Review in compliance with ICH-GCP<br><input type="checkbox"/> I.6 – Clinical trial<br><b>Required if both responses are selected</b>  |
| Will it Cost Me Anything to be in this Study** |                              | <input type="checkbox"/> VII.E.11  |
| Will I be Paid for Participating*              | <input type="checkbox"/> N/A | <input type="checkbox"/> VII.E.9-11 – Compensation plan, attach Cash Handling Plan, if needed  |

|   |                              |   |
|---|------------------------------|---|
| Do the Researchers Have Financial Interest in Study***  | <input type="checkbox"/> N/A | <input type="checkbox"/> III.3 <input type="checkbox"/> III.5   |
| 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.5 <input type="checkbox"/> XII.1   |
| What about Confidentiality *  |                              | <input type="checkbox"/> VII.C.6 <input type="checkbox"/> X.4 <input type="checkbox"/> XII  |
| 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 – Project procedures <input type="checkbox"/> ROC.1   |
| Report unexpected findings from research testing **<br>(conducted with clinical quality procedures) | <input type="checkbox"/> N/A | <input type="checkbox"/> VII.E.6 – Project procedures <input type="checkbox"/> VIII.1   |
| Is Being in this Study Voluntary*   |                              | <input type="checkbox"/> VII D.16 <input type="checkbox"/> VII.D.27   |
| • What if I Decide to Drop Out of Study*  |                              | <input type="checkbox"/> VII.E.7  |
| • 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"/> VII.B.8<br><input type="checkbox"/> VIII.1 (i.e. if becoming pregnant is an exclusion criteria or if study intervention poses a risk to a fetus)<br><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"/> I.6 – Registry, Repository, possibly Clinical Trial<br><input type="checkbox"/> VII.C.9 – DNA test results <input type="checkbox"/> VII.E.4 – Audio/video/photo<br><input type="checkbox"/> VII.E.6 – Study procedures <input type="checkbox"/> XII.4  |

**Informed Consent Document – Study Specific**

| <b>Consent Heading</b>  | <b>Element N/A</b>           | <b>Applicable HawkIRB Section</b>  |
|---|------------------------------|--|
| Registry/Repository *   | <input type="checkbox"/> N/A | <input type="checkbox"/> I.6 <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.E.5 <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"/> III.1 – NIH funded <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2 <input type="checkbox"/> X.7   |
| Studies Focusing on Violence, Abuse, Self- Injury **              | <input type="checkbox"/> N/A | <input type="checkbox"/> I.4 <input type="checkbox"/> I.14 <input type="checkbox"/> VII.E.4 <input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2 |
| <b>Signature Boxes</b>  |                              |  |
| Minor & parent ****   | <input type="checkbox"/> N/A | <input type="checkbox"/> VI.6 <input type="checkbox"/> VII.D.27  |
| Legally Authorized Representative *                               | <input type="checkbox"/> N/A | <input type="checkbox"/> VI.28 <input type="checkbox"/> VI.32 <input type="checkbox"/> VII.D.28  |
| Person Who Obtained Consent signature****<br>•if by mail or email | <input type="checkbox"/> N/A | <input type="checkbox"/> VII.D.12 <input type="checkbox"/> VII.D.16  |
| Translated ICD – Non English version****                          | <input type="checkbox"/> N/A | <input type="checkbox"/> VI.16 <input type="checkbox"/> 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](#).