# INFORMED CONSENT DOCUMENT CHECKLIST FOR SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH

Institutional Review Board and Human Subjects Office

The Informed Consent Document (ICD) or Consent Letter (CL) 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 ICD or CL and the eResearch (HawkIRB) application for social, behavioral and educational (SBER) research.
- 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 selected for monitoring

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

- Informed Consent Document/Consent Letter/Waiver of Documentation (no subject signature required on consent materials)
  - Includes template sections that are in the majority of ICDs
- Informed Consent Document/Consent Letter/Waiver of Documentation – 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** |

**SBER 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** |

| Consent Heading | N/A | Applicable IRB Section(s) |
|---|---|---|
| **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**<br>☐ **VII.D. 35 - 44** – Deception information<br>☐ **VII.E.1-2** – Randomization<br>☐ **VII.E. 3-5** – Questionnaire, survey, interview guide – add to attachments<br>☐ **VII.E.6** – Study procedures - after consent to follow up/member checking |
| | | |
| **SSN Usage ***** | ☐ **N/A** | ☐ **VII.E. 9** – Compensation ☐ **X.2** |
| | | |
| **Data sharing*** | ☐ **N/A** | ☐ **I.6** – Registry, repository, possibly Clinical Trial<br>☐ **X.4-6** ☐ **XII.1-5** |
| | | |
| **Audio/Video Recording/Photographs***** | ☐ **N/A** | ☐ **VII.E.4** ☐ **VII.E.6** – Study procedures |
| | | |
| **What are the Risks of this Study*** | | ☐ **VIII.1** ☐ **VIII.2** |
| | | |
| **What are the Benefits of this Study*** | | ☐ **IX.1** ☐ **IX.2** |
| | | |
| **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 *** | | ☐ **X.4-9** – As applicable ☐ **XII** |
| | | |
| **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** ☐ **VIII.1**<br>☐ **Protocol** – Sponsor may stop participation |
| | | |
| **What if I Have Questions *** | | ☐ **II.5** |
| | | |
| **Optional Agreements ***** | ☐ **N/A** | ☐ **VII.E.4** – Audio/video/photo ☐ **VII.E.6** ☐ **XII.1** |

**Study Specific**

| **Consent Heading** | **N/A** | **Applicable HawkIRB Section** |
|---|---|---|
| **Registry/Repository *** | ☐ **N/A** | ☐ **I.6** ☐ **XII.2** ☐ **XII.4** |
| | | |
| **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.5** ☐ **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** | ☐ **N/A**<br>☐ **N/A**<br>☐ **N/A** | ☐ **VI.6**<br>☐ **VI.28** ☐ **VI.32**<br>☐ **VII.D.28** |
| | | |
| **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.