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.

This checklist is intended for use with studies that meet the regulatory criteria of an expedited category of review (§45 CFR 46.110) and 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**

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

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**
What Will Happen During This Study *		☐ **I.4** ☐ **VII.A.1 -** Location – May need to attach a Letter of Agreement ☐ **VII.D. 37 - 45 -** Deception information ☐ **VII.E.1-2 -** Randomization ☐ **VII.E. 3-4 -** questionnaire, survey, interview guide – add to attachments ☐ **VII.E.6 -** list of procedures - after consent to follow up/member checking
SSN Usage ***	☐ **N/A**	☐ **VII.E.19** ☐ **X.2**
Data sharing*	☐ **N/A**	☐ ☐ **X.4** ☐ **X.6** ☐ **XII.4**
Audio/Video Recording/Photographs***	☐ **N/A**	☐ **VII.D.29** ☐ **VII.E.5** ☐ **X.4**
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**		**No corresponding IRB section**
Will I be Paid for Participating*	☐ **N/A**	☐ **VII.E.9 – 19 -** Compensation plan, attach Cash Handling Plan, if needed
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.1 – 3** (as applicable)
What about Confidentiality *		☐ **X.4 – 6** (as applicable)
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** ☐ **Protocol** (sponsor may stop participation)
What if I Have Questions *		☐ **II.5**
Optional Agreements ***	☐ **N/A**	☐ **VII.E.5** ☐ **VII.E.6** ☐ **XII.4**

Study Specific

Consent Heading	**N/A**	**Applicable HawkIRB Section**
Registry/Repository *	☐ **N/A**	☐ **XII.2** ☐ **XII.4**
Certificate of Confidentiality ******	☐ **N/A**	☐ **X.7** ☐ **III.1 (NIH funded)** ☐ **VIII.1** ☐ **VIII.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.29** ☐ **VI.28** ☐ **VI.32** ☐ **VII.D29** ☐ **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.