

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 *		<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
What Will Happen During This Study *		<input type="checkbox"/> I.4 <input type="checkbox"/> VII.A.1 - Location – May need to attach a Letter of Agreement <input type="checkbox"/> VII.D. 37 - 45 - Deception information <input type="checkbox"/> VII.E.1-2 - Randomization <input type="checkbox"/> VII.E. 3-4 - questionnaire, survey, interview guide – add to attachments <input type="checkbox"/> VII.E.6 - list of procedures - after consent to follow up/member checking
SSN Usage ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.19 <input type="checkbox"/> X.2
Data sharing*	<input type="checkbox"/> N/A	<input type="checkbox"/> <input type="checkbox"/> X.4 <input type="checkbox"/> X.6 <input type="checkbox"/> XII.4
Audio/Video Recording/Photographs***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.D.29 <input type="checkbox"/> VII.E.5 <input type="checkbox"/> X.4
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
Will it Cost Me Anything to be in this Study**		No corresponding IRB section
Will I be Paid for Participating*	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.9 – 19 - 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
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.6	<input type="checkbox"/> XII.1 – 3 (as applicable)
What about Confidentiality *		<input type="checkbox"/> X.4 – 6 (as applicable)	
Is Being in this Study Voluntary*		<input type="checkbox"/> VII.D.29	
• What if I Decide to Drop Out of Study*		<input type="checkbox"/> VII.E.6	
• 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"/> VIII.1 <input type="checkbox"/> Protocol (sponsor may stop participation)	
What if I Have Questions *		<input type="checkbox"/> II.5	
Optional Agreements ***	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.E.5	<input type="checkbox"/> VII.E.6 <input type="checkbox"/> XII.4

Study Specific

Consent Heading	N/A	Applicable HawkIRB Section			
Registry/Repository *	<input type="checkbox"/> N/A	<input type="checkbox"/> XII.2	<input type="checkbox"/> XII.4		
Certificate of Confidentiality ****	<input type="checkbox"/> N/A	<input type="checkbox"/> X.7	<input type="checkbox"/> III.1 (NIH funded)	<input type="checkbox"/> VIII.1	<input type="checkbox"/> VIII.2
Studies Focusing on Violence, Abuse, Self- Injury **	<input type="checkbox"/> N/A	<input type="checkbox"/> I.4	<input type="checkbox"/> I.5	<input type="checkbox"/> VII.E.4	<input type="checkbox"/> VII.E.6 <input type="checkbox"/> VIII.1 <input type="checkbox"/> VIII.2
Signature Boxes					
Minor & parent ****	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.6	<input type="checkbox"/> VII.D.29		
Legally Authorized Representative *	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.28	<input type="checkbox"/> VI.32	<input type="checkbox"/> VII.D29	
Person Who Obtained Consent signature**** •if by mail or email	<input type="checkbox"/> N/A	<input type="checkbox"/> VII.D.29	<input type="checkbox"/> VII.D.30		
Translated ICD – Non-English version****	<input type="checkbox"/> N/A	<input type="checkbox"/> VI.16	<input type="checkbox"/> VII.D.29	<input type="checkbox"/> VII.D.30	