# https://erica.research.utah.edu/Common/_erica/Custom/Images/logos/irb.gif

# INVESTIGATOR SELF-ASSESSMENT CHECKLIST

**Social and Behavioral Sciences**

The purpose of the Investigator Self-Assessment Checklist is to determine that research is being conducted properly with adherence to Federal Regulations (45 CFR 46) and University of Utah IRB Policy for the protection of human participants. The IRB auditor will be available to assist you and answer any questions you may have.

This Self-Assessment is separated into sections appropriate for social and behavioral science studies. Some sections may not be application to all studies.

**GENERAL INFORMATION**

|  |  |
| --- | --- |
| Principal Investigator: |  |
| **Campus address/phone#:** |  |
| **Co-Investigator(s):** |  |
| **E-mail address/phone#:** |  |
| **Study Coordinator(s)** |  |
| **E-mail address/phone#:** |  |
| Study Staff changes since last continuing review? | [ ]  **Yes** [ ]  **No** |
| If yes, was amendment submitted to IRB? | [ ]  **Yes** [ ]  **No [ ]  N/A** |
| Name of person completing this checklist |  |
| **IRB Protocol Number** |       |
| Study Title |  |
| Institution/Department | [ ]  U of Utah Health Sciences [ ]  U of Utah Main Campus[ ]  VAMC [ ]  PCMC [ ]  Shriners |
| **Date checklist completed** |  |
| **Sponsor/Name:**       | [ ]  Industry [ ]  Government [ ]  Internal/Department[ ]  Foundation [ ]  Other:       |
| **Date of IRB Initial Approval:** |  |
| **Total # Enrollment at this site** | #Approved:       #Enrolled to date:       |

**REGULATORY DOCUMENTATION**

Every research study should maintain regulatory documentation on file in order to verify that regulatory requirements to conduct research are met. Some studies require different regulatory documents, depending on the type of study and sponsor. Review your regulatory documents and complete this section according to the requirements that apply to your study.

Some studies may choose to maintain regulatory documentation electronically or on paper. In either case, documentation should be organized and accessible in such a way that an outside auditor could view and assess the documentation easily and securely without violating University or sponsor privacy, confidentiality, and data access requirements.

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|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Is the approved protocol on file? (Original and all previously approved versions)
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Are copies of CVs/resumes/licenses/certificates for the PI, Co-PI, faculty sponsor, and study staff on file? (updated within the past two years)
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Are they signed and dated or labeled with a version date?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is there a participant enrollment log or spreadsheet?

*See the Participant Selection Criteria section for more details regarding this requirement.* | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Is the participant enrollment log complete and up-to-date?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is there a data monitoring log?

*See the Data Monitoring section for more details regarding this requirement.* | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Is the data monitoring log complete?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is there a staff signature and delegation of responsibilities log? *See the Delegation of Responsibilities section for more details regarding this requirement.*
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Is the staff signature and delegation log complete and up-to-date?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is the grant application on file?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is all correspondence to and from the sponsor on file?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Are copies of training completion certificates for the PI, Co-PI, and study staff on file? (human participant research training, study specific training, HIPAA training, etc.)
 | [ ]  Yes[ ]  No[ ]  N/A |  |
| 1. Is there a staff training log?
 | [ ]  Yes[ ]  No[ ]  N/A |  |
| * 1. Is the staff training log complete and up-to-date?
 | [ ]  Yes[ ]  No[ ]  N/A |  |

**IRB DOCUMENTATION**

Every research study should maintain IRB documentation on file in order to verify that IRB requirements to conduct research are met. Some studies require different IRB documents, depending on the type of study and sponsor. Review your IRB documents and complete this section according to the requirements that apply to your study.

Some studies may choose to maintain IRB documentation electronically or on paper. In either case, documentation should be organized and accessible in such a way that an outside auditor could view and assess the documentation easily and securely without violating University or sponsor privacy, confidentiality, and data access requirements.

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|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Is all correspondence to and from the IRB on file? (emails, submissions/applications, approval letters, revision letters, expiration notices, etc.)
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. List the **continuing reviews** by approval date that have occurred since study initiation.
 | LIST:       |
| * 1. Is each IRB approved continuing review application and related correspondence on file?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Was each continuing review application submitted on time (between 45-60 days of expiration)?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Was there any lapsed period(s) between approval date and expiration date?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * + 1. If yes, was any participant enrolled or did any other study procedures occur during this lapsed period?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * + 1. If yes, was a deviation report form submitted to the IRB?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. List the **amendments** by approval date and amendment title that have been submitted since study initiation. Include amendments that were submitted *with* continuing review applications.
 | LIST:       |
| * 1. Is each IRB approved amendment application and related correspondence on file?
 | [ ]  Yes[ ]  No[ ]  N/A |  |
| * 1. Were any changes to the study initiated prior to IRB approval of an amendment?
 | [ ]  Yes[ ]  No[ ]  N/A |  |
| * + 1. If yes, was a deviation report form submitted to the IRB?
 | [ ]  Yes[ ]  No[ ]  N/A |  |

**UNANTICIPATED PROBLEM & DEVIATION REPORTING**

The University of Utah IRB requires researchers to submit reports on events that may represent unanticipated problems involving risks to participants and others (UPs) including unexpected, related adverse events. Researchers are required to submit the report form as soon as possible after the PI learns of the event, but in all cases within 10 working days.

UPs are defined as any incident, experience or outcome that meets all of the following criteria:

* Unforeseen (not expected by the researcher or the research participant) given the research procedures and the participant population being studied; and
* Related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
* Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

For more information regarding this policy, visit the IRB website at <http://www.research.utah.edu/irb/adverse/problems.html>.

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|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. List the **report forms** by submission date, report form title, and IRB determination that have been submitted since study initiation.
 | LIST:      [ ]  None |
| * 1. Is each report form and related correspondence on file?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Did any of the report forms require corrective or preventive actions to be completed?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * + 1. If yes, were the corrective and preventive actions completed?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Have there been any problems or events that should have been reported promptly to the IRB that were not reported?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. If yes, what is the reason that a report form was not promptly submitted?
 |       |
| 1. Is there documentation that the PI has evaluated all problems and events for this study to determine the need to report them promptly?
 | [ ]  Yes[ ]  No[ ]  N/A |  |

**PARTICIPANT RECRUITMENT PROCEDURES**

Recruitment methods, including advertisements, must not interfere with the equitable selection of participants and must adhere to IRB policy. Additionally, the IRB considers recruitment to represent a part of the consent process, and thus recruitment must not violate the regulatory requirements of informed consent.

For more information about the IRB policy for “Recruitment Methods & Advertisements”, visit the IRB website at <http://www.research.utah.edu/irb/guidelines/investigator_guidance.html>.

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Are recruitment methods described in the protocol and/or IRB application?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. How are potential participants identified? *Check all that apply.*
 | [ ]  Record Review[ ]  In person[ ]  Database[ ]  Recruitment materials (flyers, recruitment letters, etc.)[ ]  Other:      [ ]  N/A |       |
| 1. Who makes initial contact with potential participants? *Check all that apply.*
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:      [ ]  N/A |       |
| 1. How is initial contact made? *Check all that apply.*
 | [ ]  Phone call[ ]  In person[ ]  Letter/Email[ ]  Other:      [ ]  N/A |       |
| 1. If recruitment materials are used, specify. *Check all that apply.*
 | [ ]  Media advertisements[ ]  Flyers[ ]  Websites or web postings[ ]  Letters/Emails[ ]  Other:      [ ]  N/A |       |
| 1. Have all recruitment materials been approved by the IRB?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Are all approved recruitment materials on file? (Original and all previously approved versions)
 | [ ]  Yes[ ]  No[ ]  N/A |       |

**PARTICIPANT SELECTION CRITERIA**

Appropriate inclusion and exclusion criteria for research participants are essential in order to ethically justify human subject research. Inclusion and exclusion criteria should be clearly stated and reasonable. Poorly specified inclusion/exclusion criteria may result in inadvertent exclusion of eligible research subjects and an imbalance of or inappropriate enrollment of research subjects.

Randomly choose 5 participant files for inspection. Review the study files for the participants you have chosen for inspection and complete the following.

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Is there a method of documenting that participants meet inclusion/exclusion criteria?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Was the participant included/excluded appropriately? *Answer for each participant below.*
 |
| Participant #1:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #2:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #3:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #4:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #5:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. If ‘No’ for any participant, was a deviation report form submitted to the IRB?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is there documentation of who (name and date) verified each participant’s eligibility for inclusion in the study?
 | [ ]  Yes[ ]  No[ ]  N/A |       |

**INFORMED CONSENT**

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. Persons obtaining consent from participants must be qualified and trained to conduct this process. The informed consent process may involve the following types of documents:

* Adult informed consent document
* Parental permission document
* Assent document
* Consent cover letter
* Consent script

***Part I***

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. List the versions\*of the consent/parental permission/assent document(s) are there since the beginning of the study.Provide the approval and expiration date for each version of the document(s).
 | LIST:       |
| 1. Are all original copies of the IRB approved documents on file?
 | [ ]  Yes[ ]  No[ ]  N/A |       |

***\**** *Every consent form approved since the original submission results in a new version. Version does not refer to the number of consent forms being used at a given time, such as a consent form for each type of study population (e.g. healthy volunteers, adult participants, minors).*

***Part II***

Randomly choose 5 participant files for inspection. Using these participants files, complete the information below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Participant study number:** | **Type of Document Used** | **Participant / Parent / LAR****signed** | **Date signed** | **Person Obtaining Consent signed** | **Date signed** | **If a waiver of documentation of consent was used (no participant signatures obtained), describe how you documented consent for the participant:** |
| Participant #1:      |       | [ ] Y | [ ] N |       | [ ] Y | [ ] N |       |       |
| Participant #2:      |       | [ ] Y | [ ] N |       | [ ] Y | [ ] N |       |       |
| Participant #3:      |       | [ ] Y | [ ] N |       | [ ] Y | [ ] N |       |       |
| Participant #4:      |       | [ ] Y | [ ] N |       | [ ] Y | [ ] N |       |       |
| Participant #5:      |       | [ ] Y | [ ] N |       | [ ] Y | [ ] N |       |       |

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Were any expired, non-approved, or invalid consent documents used?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. If yes, was a deviation report submitted to the IRB?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Did each participant receive a copy of the signed consent document (or of the un-signed consent document if a waiver of documentation of consent was used)?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. Is there documentation in the study record that the participants received a copy of the consent?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is there documentation that a consent process occurred with each participant and that questions were answered before signing the consent or agreeing to participate?
 | [ ]  Yes[ ]  No[ ]  N/A |       |

 **SOURCE DOCUMENTATION & DATA MANAGEMENT**

Source documentation is considered the first or original recording of any observation made or data generated about a participant while that person is enrolled in a study. The recording of source information can occur on any medium and anyone interacting with the participant while in the study can generate a source document. For example, a source document could be a health record, a questionnaire or survey, an audio or video recording, etc.

Research data is often transcribed from a source document into another format, such as a data collection worksheet, a spreadsheet, a database, or a written transcript of audio files, for data management and analysis. Occasionally, transcription of source documentation into research data is not necessary, as the source document is acting as the research record directly.

Randomly choose 5 participant files for inspection. Using these participants files complete the information below.

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Is there complete source documentation for each participant?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Has the research data been **completely** transcribed from the source documentation? *Answer for each participant below.*
 |
| Participant #1:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #2:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #3:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #4:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #5:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Has the research data been **accurately** transcribed from the source documentation? *Answer for each participant below.*
 |
| Participant #1:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #2:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #3:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #4:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| Participant #5:       | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. If errors in the data were identified, is there documentation of who identified the error and if/how it should be corrected?
 | [ ]  Yes[ ]  No[ ]  N/A |       |

**DATA MONITORING**

For more information about data monitoring, visit the IRB website at <http://www.research.utah.edu/irb/guidelines/investigator_guidance.html> for the following topics:

* Data and Safety Monitoring
* Privacy and Confidentiality in Research
* HIPAA Privacy Rule and Authorization
* Audio/Multimedia Recordings
* Certificates of Confidentiality

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Are privacy and confidentiality protections described in the protocol and/or IRB application?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Have any deviations from the privacy and confidentiality protections occurred?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Have any confirmed breaches of privacy or confidentiality occurred?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. If yes, was the breach reported to the IRB via the report form?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| 1. Is a data monitoring plan described in the protocol and/or IRB application?
 | [ ]  Yes[ ]  No[ ]  N/A |       |
| * 1. How has study data and documentation been monitored throughout the study? (documented instances of monitoring) *Check all that apply.*
 | [ ]  Periodic review and confirmation of participant eligibility[ ]  Periodic review of informed consent documentation [ ]  Periodic review of the transfer / transcription of data from the original source to the research record [ ]  Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB[ ]  Other:      [ ]  No monitoring has occurred |       |
| * 1. Who has conducted monitoring of the study data and documentation? *Select all that apply.*
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Study Monitor/Auditor[ ]  Independent Physician, Faculty or Staff Member[ ]  Other:      [ ]  No monitoring has occurred |       |
| * 1. How often has the study data and documentation been monitored? (documented instances of monitoring)
 | Response:       |       |

**DELEGATION OF RESPONSIBILITIES**

The Principal Investigator has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the University of Utah Institutional Review Board. Delegation of responsibility must be made to qualified and trained investigators and study staff.

For a full list of Principal Investigator Responsibilities, visit the IRB website at <http://www.research.utah.edu/irb/submissions/submit_study.html>.

|  |  |
| --- | --- |
|  | **Comments***If your answer indicates a problem, a need for clarification, or N/A, describe the problem below:* |
| 1. Who prepares the IRB applications and documents?
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:       |       |
| 1. Who assesses unanticipated problems and deviations?
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:       |       |
| 1. Who conducts the informed consent process?
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:       |       |
| 1. Who assesses participant eligibility?
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:       |       |
| 1. Who has access to view participant research data?
 | [ ]  PI[ ]  Co-Investigator[ ]  Study Staff[ ]  Other:       |       |
| 1. If the PI has delegated any of the above tasks, is there written documentation that the PI remains actively involved in all aspects of the research?
 | [ ]  Yes[ ]  No[ ]  N/A |       |