# 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**

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| 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>.

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|  | | **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.

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|  | | **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***

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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 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.

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| **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 |  |  |

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|  | | **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.

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|  | | **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

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|  | | **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>.

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|  | | **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 |  |