Form Submission Checklists

A Forms

Definition: Greater than Minimal Risk – Studies that do not qualify as "minimal risk" nor for expedited review under the federal regulations are usually considered greater than minimal risk. Greater than minimal risk studies usually involve medical procedures or devices or create some high degree of discomfort for participants. This discomfort can be physical, emotional, social, or psychological. Studies in this category should be completed on the following forms: A1 and A2 Forms.

A1 Form: Greater Than Minimal Risk

- Original A1 form
- PI/Advisor Signature
- Department Chair Signature
- Dean's Signature
- PI Assurance*
- Conflict of Interest forms for all investigators*
- CV/Bio of the PI
- CV/Bio of all investigators
- CITI Certification for PI
- CITI Certification for all investigators
- Consent Documents

Student Investigators must also submit:

- RCR Certification (*Provide justification from Dept. Chair if not a requirement*.)
- CITI Certification
- Thesis/Dissertation Committee Approval Sheet
- Copy of the Thesis/Dissertation Proposal
- CV/Bio

Additional Items as Applicable:

- Survey Instruments
- Letters of Support/Collaboration
- Assent Documents/Parent Consent (*for participants less than 18 years of age.*)
- Recruitment Fliers/Materials
- HIPAA Authorization (if applicable)

A2 Form: Continuation/Annual Renewal of Greater than Minimal Risk Studies

- Original A2 form
- PI/Advisor Signatures
- Recent literature/published findings since last IRB annual review.
- Clean copy of consent document(s) to be used for the next approval cycle.
- Copy of HIPAA Authorization (if still consenting participants)
- Current IRB-approved executed consent document (with participant signature) acquired during the last approval cycle.
- Copy of adverse events and summaries (if applicable).
- Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.
- For PIs/All Investigators: Current CITI
- For PIs/All Investigators: Copy of conflict of interest form if changed since last IRB review.
- Copy of current grant non-competing or competing continuation grant application submitted to the agency. If this is a no cost extension, provide a copy of that request.
- Survey Instruments (if applicable).

**Please note that the PI Assurance and Conflict of Interest Forms must be completely filled out and signed.*

Form Submission Checklists
B Forms

B1 Form: Chart Reviews/HIPAA - Continuation

Original B1 form with signatures
HIPAA Training Certification via HUH Compliance Office for all investigators and personnel. Contact Meredith Harrison.*
CITI for all investigators and personnel.
CV/Bio for all investigators and personnel.

Form Submission Checklists

C Forms

Definition: Minimal Risk – As defined at 45 C.F.R. § 46.102(i), "Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Minimal risk studies that involve vulnerable populations (children, pregnant women, fetuses and neonates, human in vitro fertilization, prisoners, economically or educationally disadvantaged participants, cognitively impaired persons) must go before the Full Board for consideration.

C1 Form: Minimal Risk Studies and Socio-Behavioral Thesis/Dissertation Research

Original C1 form
PI/Advisor Signature
Dept. Chair Signature
Dean's Signature
PI Assurance*
Conflict of Interest forms for all investigators*
CV/Bio of the PI
CV/Bio of all investigators
CITI Certification for PI
CITI Certification for all investigators
Consent Documents

Student Investigators must also submit:

RCR Certification (*Provide justification from Dept. Chair if not a requirement.*)
CITI Certification
Thesis/Dissertation Committee Approval Sheet
Copy of the Thesis/Dissertation Proposal

Additional Items as Applicable:

Survey Instruments
Letters of Support/Collaboration
Assent Documents/Parent Consent (*for participants less than 18 years of age.*)
Recruitment Fliers/Materials

C2 Form: Continuation/Annual Renewal of Minimal Risk Studies/Socio-Behavioral Student Research

Original C2 form
PI/Advisor Signatures
Recent literature/published findings since last IRB annual review.
Clean copy of consent document(s) to be used for the next approval cycle.
Current IRB-approved executed consent document (with participant signature) acquired during the last approval cycle.
Copy of adverse events and summaries (if applicable).
For PIs/All Investigators: Current CITI
For PIs/All Investigators: Copy of conflict of interest form if changed since last IRB review.
Copy of current grant non-competing or competing continuation grant application submitted to the agency. If this is a no cost extension, provide a copy of that request.
Survey Instruments (if applicable).

**Please note that the PI Assurance and Conflict of Interest Forms must be completely filled out and signed.*

Form Submission Checklists
D Form

D1Form: Exempt Studies and Studies Not Involving Human Participants

Original D1 form
PI/Advisor Signature
Dept. Chair Signature
Dean's Signature
PI Assurance Form*
CV/Bio of the PI
CV/Bio of all investigators
CITI Certification for PI
CITI Certification for all investigators
Consent Documents (if applicable)

Student Investigators must also submit:

RCR Certification
CITI Certification
Thesis/Dissertation Committee Approval Sheet
Copy of the Thesis/Dissertation Proposal
CV/Bio of the Student Investigator

Additional Items as Applicable:

Letters of Support/Collaboration
Recruitment Fliers/Materials

**Please note that the PI Assurance must be completely filled out and signed.*