

# Form Submission Checklists

## A 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

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#### ***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

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#### ***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).

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***\*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

- 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.
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### B2 Form: Continuation/Annual Renewal for Chart Reviews/HIPAA

- Original B2 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.
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\*Meredith Harrison, JD

Chief Compliance Officer for Health Sciences and Privacy Officer

202-865-7485 (office)

mharrison@huhosp.org

# Form Submission Checklists

## C Forms

### 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

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#### *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

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#### *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).

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*\*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)

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#### *Student Investigators must also submit:*

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

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#### *Additional Items as Applicable:*

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- Letters of Support/Collaboration
- Recruitment Fliers/Materials

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