IRB Submission Decision Trees

The decision trees are intended as a guide, to assist researchers in identifying the IRB Application(s) required for a new IRB submission. During the screening and review process, the IRB may require researchers to complete additional forms or documents if it is determined that the documents are required. Always obtain forms and templates from IRBNet or the Research Center.

Researchers should also consult with their research supervisor when preparing for IRB submission.

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IRB Application Decision Tree

This decision tree is intended to assist researchers in identifying the IRB Application(s) required for a new IRB submission. Once researchers have identified the main application(s), the researcher should consult the additional decision trees for supplemental forms, informed consent/assent form(s), and other supporting documents in identifying the additional documents that will be required for IRB submission. During the screening and review process, the IRB may require researchers to complete additional forms or documents if it is determined that the documents are required. Always obtain forms and templates from IRBNet or the Research Center.

Will you, in any way, interact with or contact human participants? Yes → Are you utilizing pre-existing records in your research study? Yes → The following documents are required for IRB submission: • IRB Application • Supplemental Form H

No → The following documents are required for IRB submission: • IRB Records Based Research Application

Identify which supplemental forms, informed consent/assent forms, and supporting documents are required for IRB submission.

Supplemental Form Decision Tree → Informed Consent/Assent Form(s) Decision Tree → Other Supporting Documents Decision Tree

Version Date: 01 July 2011
Supplemental Forms Decision Tree

This decision tree is intended to assist researchers in identifying the supplemental form(s) required for IRB submission. During the screening and review process, the IRB may require researchers to complete additional forms or documents if it is determined that the documents are required. Always obtain forms and templates from IRBNet or the Research Center.

Will the research study pose “more than minimal or unknown” risk of harm to participants or include the collection sensitive data?

Yes → The following is required for IRB Submission:
- Supplemental Form A—Risk Addendum

No → Supplemental Form A is not required. However, the IRB will make the final determination on risk and sensitivity. The researcher may be requested to complete this form.

Is a field test (expert review) required for your research study?

Yes → The following is required for IRB Submission:
- Supplemental Form B—Field Test Procedures & Results
  Your school/committee or the IRB may determine that a field test (expert review) is appropriate for your study. Once the field test is completed, please complete this supplemental form to include with your submission to the IRB office.

No → Supplemental Form B is not required. However, the IRB or the school will make the final determination regarding field test (expert review) requirements.

Identify Additional Supplemental Forms

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Will the research target or include children or minors? Please note that some states set ages other than 18 as the legal age. It is incumbent on the researcher and the mentor to observe the legal requirements for the jurisdiction in which the research will be conducted.

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form D—Research Involving Children/Minors

- **No**
  - Supplemental Form D is not required. However, the researcher may be requested to complete this form.

Will the research target potentially vulnerable populations?

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form E—Research Involving Vulnerable Populations

- **No**
  - Supplemental Form E is not required. However, the IRB will make the final determination. The researcher may be requested to complete this form.

Will the research target or include children or minors? Please note that some states set ages other than 18 as the legal age. It is incumbent on the researcher and the mentor to observe the legal requirements for the jurisdiction in which the research will be conducted.

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form C—Research Involving Prisoners

- **No**
  - Supplemental Form C is not required. However, the researcher may be requested to complete this form.

If a participant becomes incarcerated during his or her involvement in the study, the IRB must approve the inclusion of prisoners in this study in order for the person to continue to participate in the study.
For research that includes an informed consent/assent process, are you requesting that the participants not sign the informed consent document or not be exposed to some of the required elements of the informed consent process?

If your research involves direct interaction with participants or identifiable records research, Capella University’s requires researchers to obtain and document informed consent. However, it may occasionally be in the best interests of the participants not to be required to sign the informed consent/assent document or not to be exposed to some elements of the informed consent process/document.

The following is required for IRB Submission:
- Supplemental Form F—Request for Waiver of Documentation or Elements of Informed Consent

Supplemental Form F is not required. However, the researcher may be requested to complete this form.

Ordinarily, Capella University’s IRB requires that doctoral researchers develop an informed consent process and use the informed consent/assent templates provided by the university.

Will the research include the recruitment of Capella participants or access Capella data?

If yes, the following is required for IRB Submission:
- Supplemental Form G—Capella Research Request

A determination will be made as to whether the request can be granted. Permission must be obtained prior to recruiting Capella alumni, learners, faculty, or staff for research or accessing Capella data or records. Read more about this process.

Supplemental Form G is not required. However, the IRB will make the final determination. The researcher may be requested to complete this form.

Will you be directly interacting with participants and utilizing pre-existing records?

If yes, the following is required for IRB Submission:
- Supplemental Form H

If you plan to access records solely for the purpose of recruiting potential participants, do not complete this form.

Supplemental Form H is not required. However, the researcher may be requested to complete this form.

Identify Additional Supplemental Forms

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Are there any relationships that could compromise the integrity of the research?

Yes

It is the ethical responsibility for all researchers to provide full disclosure of all potential conflicts of interest, including, but not limited to, significant financial relationships, and the financial interests they create, personal/professional relationships, business relationships, or other conflicts that affect the rights and welfare of human participants in research.

The following is required for IRB Submission:
- Supplemental Form I—Conflict of Interest Management Plan

No

Supplemental Form I is not required. However, the researcher may be requested to complete this form.

Identify Additional Supplemental Forms

Will the research include non-native English speakers?

Yes

The following is required for IRB Submission:
- Supplemental Form J—Use of Translations and Interpreters

You must translate your Informed consent form and any other materials for the participants. As documents may require revision during the IRB review process, translation of documents should occur after IRB review. Conditional approval will be granted for studies requiring translated documents. Full approval will be granted once the IRB receives a copy of the translated document(s) along with a signed copy of Supplemental Form K: Certification of Translation.

No

Supplemental Form J is not required. However, the researcher may be requested to complete this form.

Identify Additional Supplemental Forms

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Continued

**Will you intentionally mislead participants or withhold full disclosure as to the nature of the research or elements of informed consent?**

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form F—Request for Waiver of Documentation or Elements of Informed Consent
    - Supplemental Form L—Research Involving the Use of Deception
  - Per the federal regulations, there are strict guidelines that must be met in order to use deception in your research. If your study design includes the use of deception, you must also complete Supplemental Form F to request waiver of elements of informed consent. All studies that use deception will be reviewed by the Full IRB committee.

- **No**
  - Supplemental Form L is not required. However, the IRB will make the final determination. The researcher may be requested to complete this form.

**Will the research study include a pilot study?**

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form M
  - You must gain IRB approval prior to conducting any study (including pilot studies) involving human participants or their records.

- **No**
  - Supplemental Form M is not required. However, the researcher may be requested to complete this form.

**Will the research target cognitively impaired persons?**

- **Yes**
  - The following is required for IRB Submission:
    - Supplemental Form N—Research Involving Cognitively Impaired Persons

- **No**
  - Supplemental Form N is not required. However, the researcher may be requested to complete this form.
Supplemental Forms Decision Tree

Will you conduct any research procedures outside of the United States?

Yes

The following is required for IRB Submission:
- Supplemental Form O—International Research

No

Supplemental Form O is not required. However, the IRB will make the final determination. The researcher may be requested to complete this form.

Identify Additional Supplemental Forms

Will you be engaging in action research with a community or organization?

Yes

The following is required for IRB Submission:
- Supplemental Form P

No

Supplemental Form P is not required. However, the researcher may be requested to complete this form.

Complete these decision trees if you have not already done so.

IRB Application Decision Tree

Informed Consent/Assent Form(s) Decision Tree

Additional Supporting Documents Decision Tree

Note: Most professional doctorate programs involve the action research.
Informed Consent/Assent Forms Decision Tree

This decision tree is intended to assist researchers in identifying the informed consent/assent form(s) required for IRB submission. Capella University’s IRB requires all researchers to use an informed consent/assent form document template if the research will involve human participants. The templates have been designed to assist researchers in providing the appropriate information to participants in accordance to the federal Common Rule (45 CFR 46.116). Remember, you cannot obtain informed consent from any participants until you receive Capella’s IRB approval for your research study.

During the screening and review process, the IRB may require researchers to complete additional forms or documents if it is determined that the documents are required. Always obtain forms and templates from IRBNet or the Research Center.

**Are your participants adults?**
- Yes
  - Parental permission and child assent is most likely required for IRB submission:
    - Parental Permission Form
    - Child Assent Template (Ages 7-11)
    - Minor Assent Template (Ages 12-17)
  - Will you collect sensitive information from participants?
    - Yes
      - The following template may be required for IRB Submission:
        - Adult Informed Consent Template—Waiver of Documentation of Consent
        - Not all studies involving sensitive information qualify for a waiver. Please consult the IRB Office (irb@capella.edu).
      - Will you ask your participants to not sign or remove any elements the informed consent form?
        - Yes
          - The following template is required for IRB Submission:
            - Adult Informed Consent Template
        - No
          - Complete these decision trees if you have not already done so.
  - No
    - Will you ask your participants to not sign or remove any elements the informed consent form?
      - Yes
        - Complete these decision trees if you have not already done so.
      - No
        - IRB Application Decision Tree

**Will you collect sensitive information from participants?**
- Yes
  - Complete these decision trees if you have not already done so.
- No
  - Will you ask your participants to not sign or remove any elements the informed consent form?
    - Yes
      - Complete these decision trees if you have not already done so.
    - No
      - IRB Application Decision Tree

Version Date: 01 July 2011
Additional Supporting Documents Decision Tree

This decision tree is intended to assist researchers in identifying additional supporting documents required for IRB submission. During the screening and review process, the IRB may require researchers to complete additional forms or documents if it is determined that the documents are required. Always obtain forms and templates from IRBNet or the Research Center.

Are you a doctoral researcher?  
Yes  
Doctoral researchers are required to provide documentation that indicates that their research study can undergo IRB review. This documentation varies by school/program, but can include:  
- Dissertation proposal (Chapters 1-3)  
- Scientific Merit Review or Methodology Review Evaluation Forms and Notices  
- School Proposal Approval Notices  
- Milestone Completion Reports  
Please consult your research supervisor to identify the school specific requirements.

No  
Are you a faculty or staff researcher?  
Yes  
If you are a faculty or staff researcher, please consult with the Research Integrity Office (RIO) before applying to Capella’s IRB.

No  
Are the research study include a survey, interview guide, or other instrument(s)?  
Yes  
The following are additional documents required for the IRB submission:  
- Copy of the survey, interview guide, or other instrument(s)  
- If the instrument was created by someone other than the researcher and there is a copyright, a permission letter (in writing, e-mail, or purchase agreement) from the instrument’s author is required. Read more about pilot studies and field tests (expert review).

No  
Identify Additional Supporting Documents

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Will the research involve a research site for recruitment, data collection, or other purposes?  
This includes the use of a site’s directory for recruitment purposes.

Yes

Identify Additional Supporting Documents

Will you be recruiting participants by phone, e-mail, flyer, or in some other manner?  

Yes

Identify Additional Supporting Documents

Will the research involve research assistants?

Yes

Identify Additional Supporting Documents

Additional supporting documents may be required for your study depending on the research. This could include, but is not limited to,
- Additional safeguard materials
- A copy of the researcher’s resume
- A copy of the researcher’s clinical/psychiatric license
- HIPAA or FERPA authorizations

Consult your research supervisor for guidance or the IRB Office (irb@capella.edu).

Complete these decision trees if you have not already done so.

IRB Application Decision Tree
Supplemental Form Decision Tree
Informed Consent/Assent Form(s) Decision Tree

The following are additional documents required for the IRB submission:
- Authorization Request Letters to Research Sites
- Research Site Permission Letter

To be considered sufficient, permission letters from outside organizations must:
- be written on the organization’s official letterhead
- be signed by an IRB Chair (if applicable) or other official within the organization
- be dated within six months of IRB submission
- clearly state that the researcher has the organization’s permission to conduct his/her research at the organization

Read more about research site permissions in the Human Research Protections Standard Operating Procedures.

Drafts of all recruitment materials must be provided in the IRB submission, including, but not limited to,
- A draft of any flyers, advertisements, invitational e-mails or letters.
- A draft of an oral recruitment script

Read more about recruitment material in the Human Research Protections Standard Operating Procedures.

The following are additional documents required for the IRB submission:
- Signed Confidentiality Agreement

Read more about research assistant requirements in the Human Research Protections Standard Operating Procedures.