Brandeis University IRB Review Determination Tree

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge (and contribute to current academic understanding)?

Yes

Does the research involve an intervention or interaction with individuals for the use, study, or analysis of their information?

No

Does the research involve obtaining, using, studying, analyzing, or generating information or biospecimens about living individuals?

Yes

Is the information being obtained private information?

No

Does the research involve deception, prisoners, or risks/discomfort/distress beyond those the subject would encounter in daily life?

Yes

Research requires IRB approval. Submit an Initial Application.

No

Does all of the research fall into exempt research category 4?

Yes

Research requires HRPP review. Submit a Secondary Data Application.

No

Activity is not human subjects research and does not require IRB approval

No

Activity is not human subjects research and does not require IRB approval

No

Activity is not human subjects research and does not require IRB approval

No

Activity is not human subjects research and does not require IRB approval

Yes

Are the data or biospecimens identifiable, coded, or linked to the identity of the subjects in any way?—and/or—Is the information being obtained private information?

No

Does all of the involvement with the subjects fall into an exempt category?

Yes

Research requires IRB approval. Submit an Initial Application.

No

Are the data or biospecimens coded or linked to the identity of the subjects in any way?

No

Does all of the research fall into exempt research category 4?

Yes

Research requires HRPP review. Submit a Secondary Data Application.

No

Research requires HRPP review. Submit a Secondary Data Application.
The process begins with the question: “Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge (and contribute to current academic understanding)?”

From here the route splits in two directions:

**Route I: No**
- Activity is not human subjects research and does not require IRB approval.
- This route ends here.

or

**Route II: Yes**
- Does the research involve an intervention or interaction with individuals for the use, study or analysis of their information?
- Route splits in two directions:
  - **Route A: No**
    - Does the research involve obtaining, using, studying analyzing or generating information or biospecimens about living individuals?
    - Route splits in two directions:
      - **Route A1: No**
        - Activity is not human subjects research and does not require IRB approval.
        - Route ends here.
      - or
      - **Route A2: Yes**
        - Is the information being obtained private information?
        - Route splits in two directions
          - **Route A2a: No**
            - Activity is not human subjects research and does not require IRB approval
            - Route ends here.
          - or
          - **Route A2b: Yes**
            - Are the data or biospecimens coded or linked to the identity of the subjects in any way?
            - Route splits in two directions
              - **Route A2b-i: No**
                - Activity is not human subjects research and does not require IRB approval
                - Route ends here.
or

- **Route A2b-ii: Yes**
  - Does all of the research fall into exempt research category 4?
  - Route splits into 2 directions:
    - **Route A2b-ii-a: No**
      - Research requires IRB approval. Submit a Secondary Data Application.
      - Route ends here.
    - or
    - **Route A2b-ii-b: Yes**
      - Research requires HRPP review. Submit an Exempt Research Application.
      - Route ends here.

- **Route B: Yes** (continuation of Yes route)
  - Are the data (or biospecimens) identifiable, coded or linked to the identity of the subjects in any way? – and/or – Is the information being obtained private information?
  - Route splits into 2 directions:
    - **Route B1: No**
      - Activity is not human subjects research and does not require IRB approval.
      - Route ends here.
    - or
    - **Route B2: Yes**
      - Does the research involve deception, prisoners or risks/discomfort/distress beyond those the subject would encounter in daily life?
      - Route splits into 2 directions:
        - **Route B2a: No**
          - Does all of the involvement with the subjects fall into an exempt category?
          - Route ends here.
        - or
        - **Route B2a-ii: Yes**
          - Research requires HRPP review. Submit an Exempt Research Application.
          - Route ends here.
        - or
        - **Route B2b: Yes**
          - Research requires IRB approval. Submit an Initial Application.
          - Route ends here.