Expedited Reviewer Form

Indicate if the proposed research is eligible for expedited review:
[Research activities are eligible for expedited review when they meet all the expedited applicability criteria including no more than minimal risk and, fall under at least one of the expedited categories: see Expedited Categories]

(If no, proceed to Comment Field in the Finish tab to enter justification for why the study is not eligible for Expedited Review (e.g., greater than minimal risk).

○ Yes ○ No

Identify the expedited category number(s) that apply to this research proposal (e.g., 4, 5):
[see Expedited Categories]

The IRB agreed with the PI's written informed consent document and confirms that the form meets general regulatory requirements and includes required elements and applicable additional elements of informed consent (select “N/A” if waiver of informed consent requested).
[See "Federally Required Elements of Informed Consent" to review the required and additional elements of informed consent which applies to, for example, consent form, cover letter and/or phone script when used alone or in combination with a debriefing and permission to use data form when applicable.]

○ Yes ○ No ○ N/A

The requirements for Waiver of Informed Consent are met, and are appropriately documented (select "N/A" if waiver not requested).
[To help make this determination, if applicable, see the Informed Consent section to review the researcher's request and justification to waive informed consent per 45 CFR 46.116(c)(d).]

○ Yes ○ No ○ N/A

The requirements for Waiver of Signatures on Informed Consent Forms are met, and are appropriately documented (select “N/A” if waiver of doc not requested).

[To help make this determination, if applicable, see the Informed Consent section to review the researcher's request and justification to waive documentation of informed consent per 45 CFR 46.117 as well as the "Federally Required Elements of Informed Consent", if applicable.]

○ Yes ○ No ○ N/A

The requirements for use of a Medical Device are met, and are appropriately documented (select “N/A” if not a device study).

[To help make this determination, if applicable, see the Study Device Information section and the corresponding Study Device Form attachment, to review the researcher's request and justification for use of a device per 21 CFR 812.]

○ Yes ○ No ○ N/A

The requirements for involvement of Adults with Impaired Consent Capacity are met, and are appropriately documented (select “N/A” if impaired consent capacity subjects are not involved).

[To help make this determination, if applicable, see the "Impaired Consent"/"Form T" attachment to review the researcher's request and justification for recruitment of adults with impaired consent capacity per UK IRB Policy.]

○ Yes ○ No ○ N/A

The requirements for involvement of Pregnant Women, Human Fetuses and Neonates are met, and are appropriately documented (select “N/A” if pregnant women, human fetuses, and/or neonates are not involved).

[To help make this determination, if applicable, see the Pregnant Women/Fetuses/Neonates subsection to review the researcher's request and justification for recruitment of individuals within this vulnerable population per Subpart B.]

○ Yes ○ No ○ N/A

The requirements for involvement of Prisoners are met, and are appropriately documented (select “N/A” if prisoners not involved).

[To help make this determination, if applicable, see the Prisoners subsection to review the researcher's request and justification for recruitment of individuals within this vulnerable population per Subpart C.]

○ Yes ○ No ○ N/A

The requirements for involvement of Children are met, and are appropriately documented (select “N/A” if children not involved).

[To help make this determination, if applicable, see the Children subsection to review the researcher's request and justification for recruitment of individuals within this vulnerable population per Subpart D.]

○ Yes ○ No ○ N/A

The requirements for involvement of Wards of the State are met, and are appropriately documented (select “N/A” if wards of the state are not involved).

[To help make this determination, if applicable, see the Children subsection to review the researcher's request and justification for recruitment of individuals within this vulnerable population per Subpart D.]

○ Yes ○ No ○ N/A

IRB Review*

Protocol Review

Expedited Initial Review - Primary Reviewer Determinations

Review Details | XP Signature | Attachment(s) | Finish

--> Refer to this **Criteria for IRB Approval Checklist** as needed.
--> Refer to this **Elements of Informed Consent Checklist** as needed.
--> Refer to this **Reviewer Determinations Guidance** document for info about what each determination means.

Select Your Determination

- ○ Approve
- ○ Minor Revision
- ○ Full Review Required
- ○ Not Human Research
- ○ Withdrawn
- ○ Disapproved

☐ Serious/Continuing Non-compliance or Suspension/Termination.

Comments / Requested Revisions

☐ I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save | Complete Review