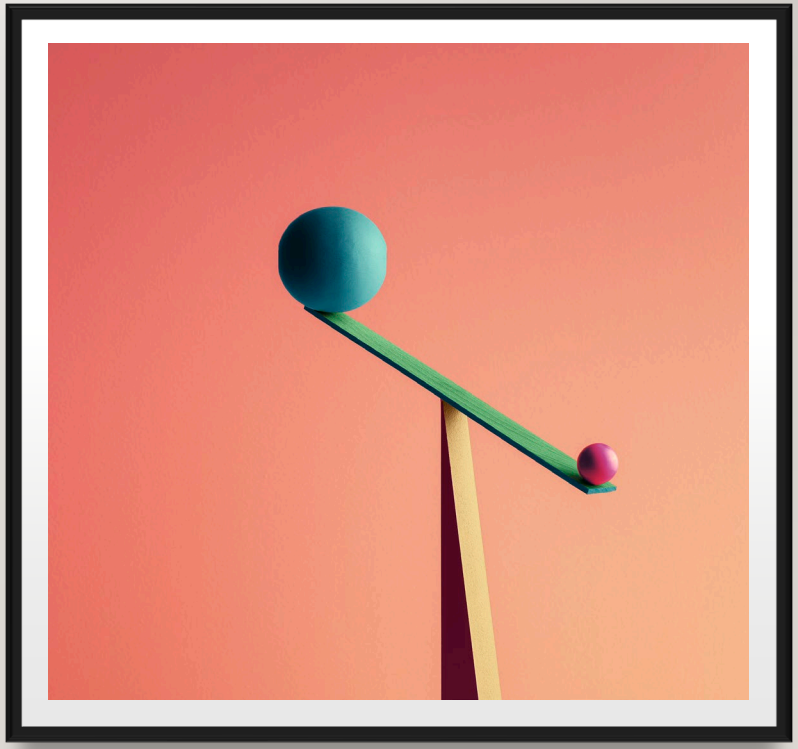
CONTINUING REVIEW

OHRP GUIDANCE

OHRP CONTINUING REVIEW GUIDANCE

- Must prepare and maintain written procedures for conducting continuing review
- When Convened, membership and quorum requirements apply
- *…responsibility to conduct continuing review at least annually, which provides an opportunity to reassess the totality of the project and assure that, among other things, risks to subjects are being minimized and are still reasonable in relation to anticipated benefits, if any, to the subjects and the knowledge that is expected to result*

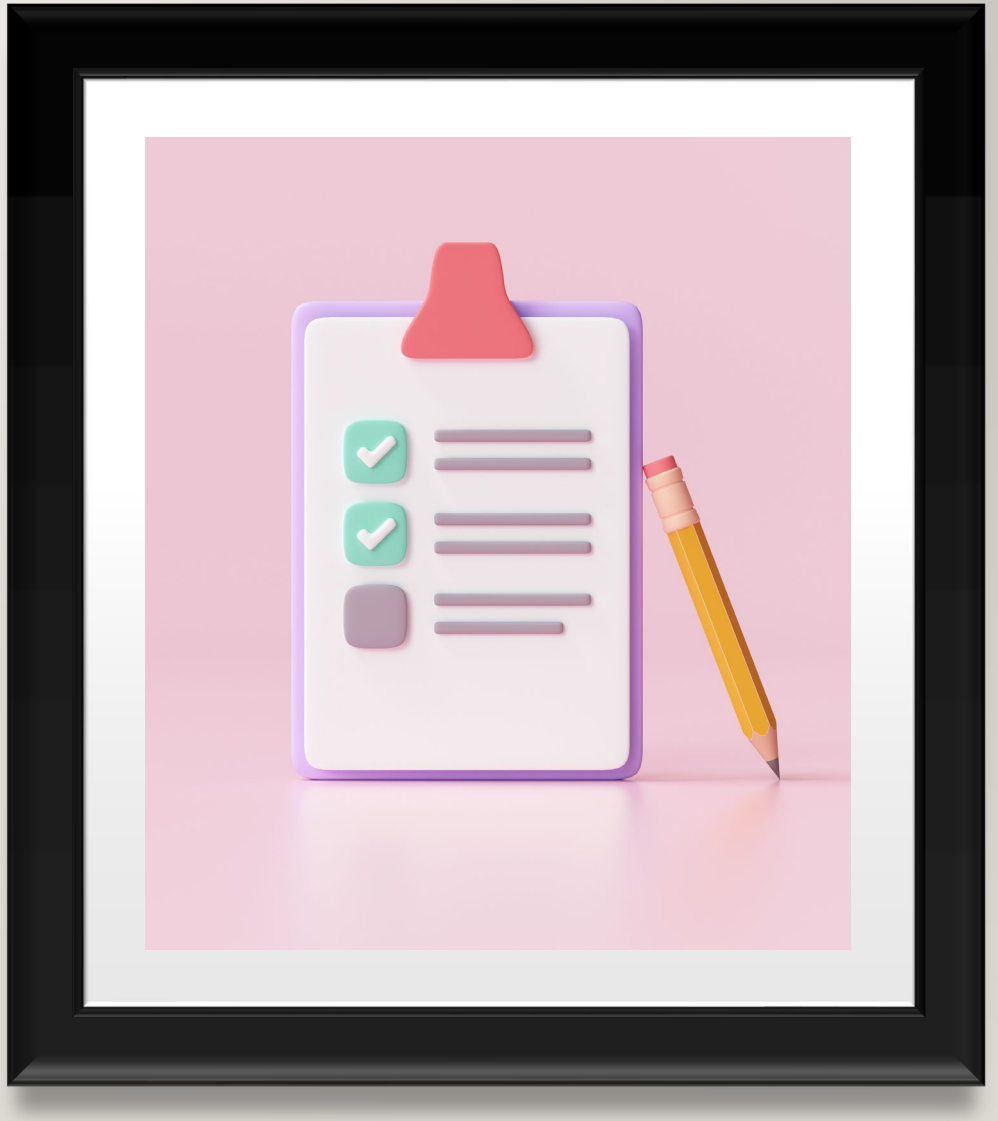


CRITERIA FOR APPROVAL (§46.111)

- Risks to subjects are minimized
- Risks are reasonable in relation to benefits
- Selection of subjects is equitable
- Informed consent is obtained
- Informed consent is documented
- Adequate provisions for monitoring data, ensuring its confidentiality and the safety of subjects
- Adequate provisions for privacy
- Safeguards for any vulnerable populations

INNOCENT UNTIL PROVEN GUILTY

- Start with presumption that research continues to meet criteria for approval
- Review any new information
- Assess previous determinations
- Assess need for revision to protocol or consent form



AREAS OF FOCUS

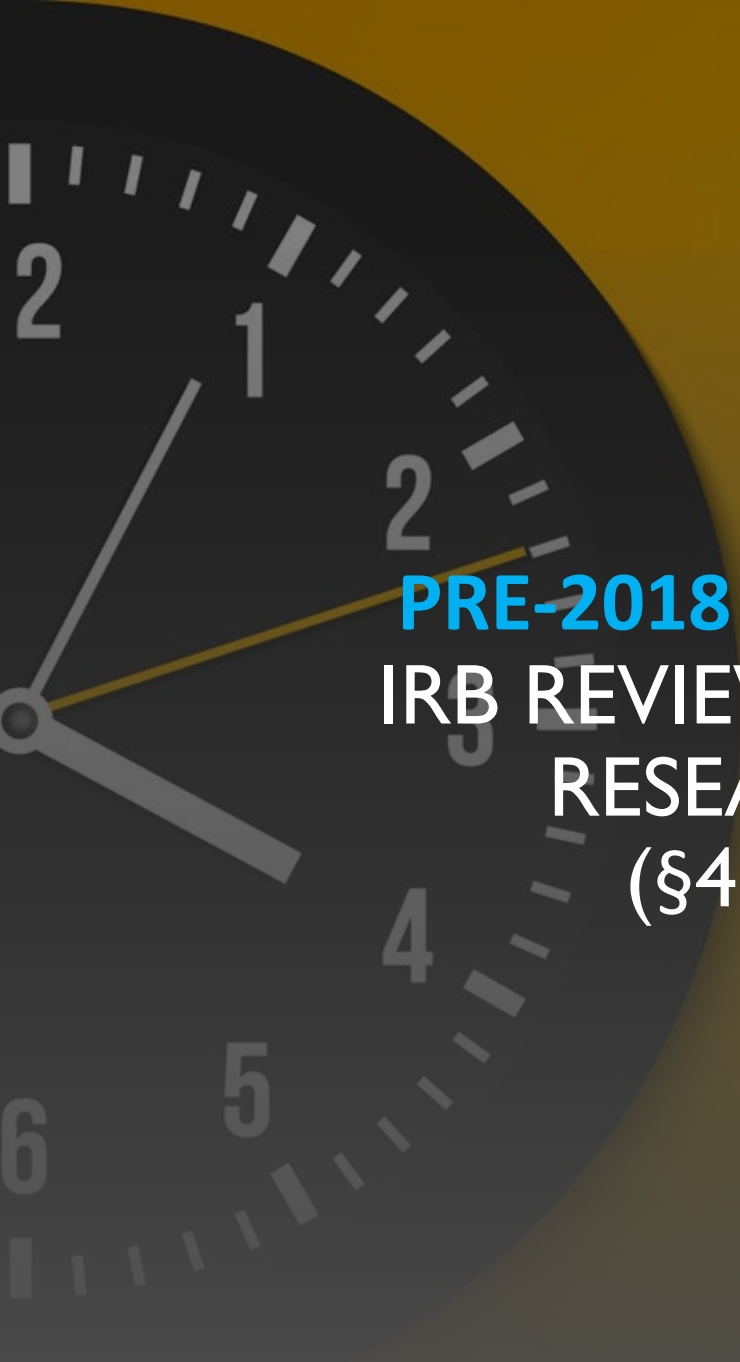
RISK	Review information that could alter IRB's previous conclusion that risks to subjects are minimized, and risks to subjects are reasonable in relation to anticipated benefits
CONSENT	Ensure approved consent document adequately addresses the elements of informed consent and describes most-current procedures (e.g., if Modification in interim)
PI or INSTITUTION ISSUES	Consider any changes to PI qualifications, reports of complaints, and changes to applicable regulations/policy and institutional resources
RESEARCH PROGRESS	Confirm progress aligns with approved protocol and assess enrollment and withdrawals

CONTINUING REVIEW ESTR SMARTFORM

4. Check the items that are true since the last IRB approval (initial review or last continuing review) for all sites approved by the Harvard IRB:

- [x] NO subjects experienced unexpected harm
- [x] Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- [x] NO subjects withdrew from the study
- [x] NO unanticipated problems involving risks to subjects or others
- [x] NO complaints about the study
- [x] NO publications in the literature relevant to risks or potential benefits
- [x] NO interim findings
- [x] NO multi-center trial reports
- [x] NO data safety monitoring reports
- [x] NO regulatory actions that could affect safety and risk assessments
- [x] NO other relevant information regarding this study, especially information about risks
- [x] In the opinion of the PI, the risks and potential benefits are unchanged
- [x] All modifications to the protocol have been submitted to the IRB
- [x] All problems that require prompt reporting to the IRB have been submitted

COMMON RULE



PRE-2018 RULE:
IRB REVIEW OF RESEARCH (§46.109)

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year

2018 RULE:
IRB REVIEW OF RESEARCH (§46.109)

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f)…

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

2018 RULE: IRB REVIEW OF RESEARCH (§46.109)

An IRB shall conduct continuing review of ***research requiring review by the convened IRB*** *at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f)…*

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

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IRB REVIEW OF RESEARCH (§46.109)

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Unless an IRB determines otherwise*, continuing review of research is not required in the following circumstances*

CONTINUING REVIEW NOT REQUIRED(§46.109)

EXPEDITED RESEARCH

RESEARCH WITH LIMITED IRB REVIEW

RESEARCH PROGRESSED TO DATA ANALYSIS

EXPEDITED APPROVAL

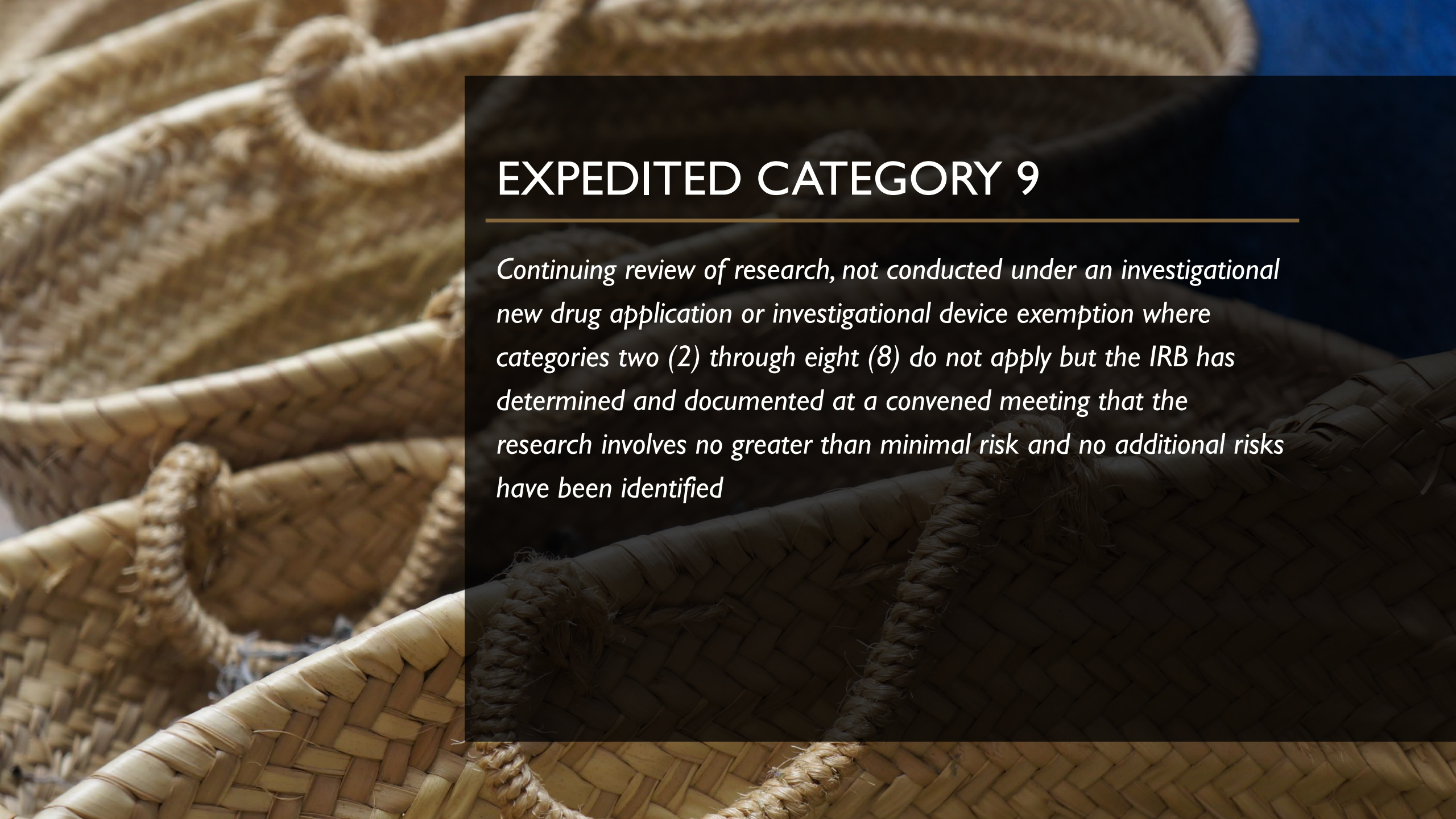
Research presents no more than minimal risk

Fits an Expedited review category

Must meet all regulatory criteria for approval

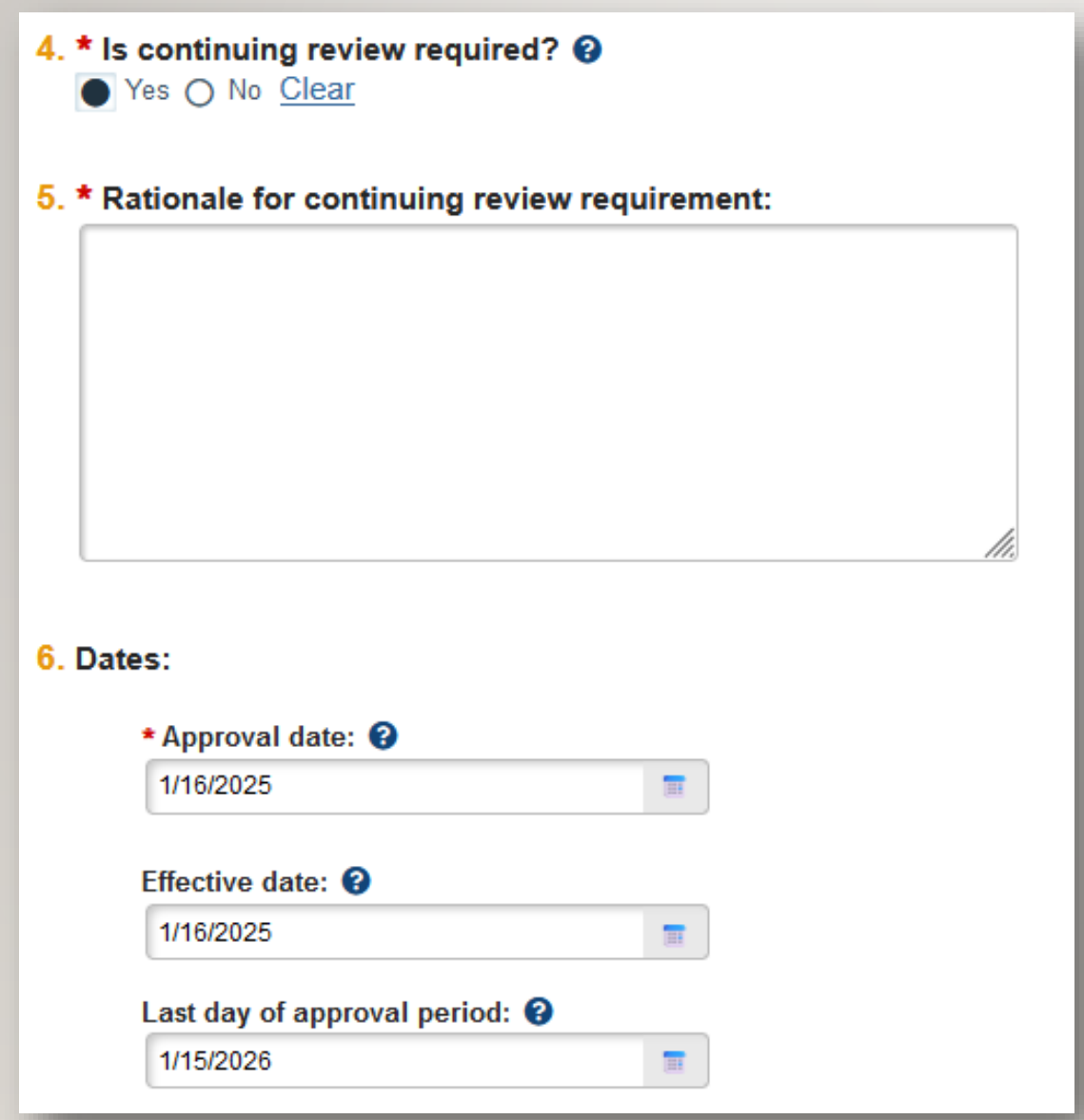
EXPEDITED APPROVAL
(MOST COMMON PROCEDURES)

- Research using surveys, interviews, educational tests not determined Exempt
- Observation of private behavior
- Voice, video, or other recording
- Secondary use of private, identifiable information
- Non-invasive procedures (e.g., saliva samples, fMRI, EEG)



EXPEDITED CATEGORY 9

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified



WHEN THE IRB DETERMINES OTHERWISE

IRB provides rationale for why Continuing Review required:

- Procedures uncommon for research portfolio
- Procedures do not fall in Expedited categories 1-7
- Multi-phase/expecting Modification
- Other institutions: policy-based requirement (e.g., every X years)

STUDY CLOSURE

- Research is permanently closed to enrollment
- All participants have completed all research-related interventions/interactions
- Collection of private identifiable information is complete
- Analyses of private identifiable information is completed

QUESTIONS?

CONTINUING REVIEW