

1. Policy Purpose Statement

Federal Regulations require an IRB to conduct substantive and meaningful continuing review of human subjects research that is within the jurisdiction of the IRB. This policy outlines the criteria for continuing review and administrative checkin.

2. Definitions

expedited review in accordance with §46.110 catbiospecimens, or
up clinical data from procedures that participants would undergo
e.

g review for any reseath that falls within the above exception

y consider to determine that continuing review is required include:
cs, procedures, or data that may be considered sensitive or
involves particularly vulnerable participants or circumstances that
erability; an investigator has minimal experience in research or the
cedures; federal guidance; other information pertaining to best
y sponsor; and/or an investigator has a history of noncompliance.
es that continuing review is required for such research, the
n thereview checklist and communicated to the investigabr in the
6.115(a)(8)).

ch research may be conducted by Expedited procedure.

that is not FDAregulated, supported by the Department of Justice
on Rule and is determined to be more than minimal risk by the

d must occur at intervals a7 (s)6 mD10.8 (o bc)8.6 (u)10.5 (.9)-4.7 4-0.7 (ID 74 >>BDC -0.004 Tc 0.0v)6.1 (o (-)-0.8 (at89a

board is required and may be conducted at intervals greater than one year and up to three (3) years if all of the following criteria are satisfied:

3.4.1. The research is not covered by a Certificate of Confidentiality.

3.4.2. The research does not involve prisoners or parolees.

3.4.3. The research has no contractual obligations or sponsor restrictions requiring an annual

3.12. When continuing review is not required by regulation or this policy, the organization will