Southeastern	
  University	
  Institutional	
  Review	
  Board
	

Standard	
  Operating	
  Procedures
	

Expedited	
  Review
	

SOP	
  #
	
  RR	
  102

c.	

	
  magnetic	
  resonance	
  imaging;	

	

d.	

	
  electrocardiography,	
  electroencephalography,	
  thermography,	
  detection	
  of	
  naturally	

occurring	
  radioactivity,	
  electroretinography,	
  ultrasound,	
  diagnostic	
  infrared	
  imaging,	
  doppler	

blood	
  flow,	
  and	
  echocardiography;	
  e.	
  moderate	
  exercise,	
  muscular	
  strength	
  testing,	
  body	

composition	
  assessment,	
  and	
  flexibility	
  testing	
  where	
  appropriate	
  given	
  the	
  age,	
  weight,	
  and	

health	
  of	
  the	
  individual.	

	

	

1.1.2.5.	
  	
  Research	
  involving	
  materials	
  (data,	
  documents,	
  records,	
  or	
  specimens)	
  that	
  have	
  been	

collected,	
  or	
  will	
  be	
  collected	
  solely	
  for	
  non
-‐research	
  purposes	
  (such	
  as	
  medical	
  treatment	
  or	
  diagnosis).	

(NOTE:	
  Some	
  research	
  in	
  this	
  category	
  may	
  be	
  exempt	
  from	
  the	
  HHS	
  regulations	
  for	
  the	
  protection	
  of	

human	
  subjects.	
  45	
  CFR	
  46.101(b)(4).	
  This	
  listing	
  refers	
  only	
  to	
  research	
  that	
  is	
  not	
  exempt.)	

	

	

1.1.2.6.	
  	
  Collection	
  of	
  data	
  from	
  voice,	
  video,	
  digital,	
  or	
  image	
  recordings	
  made	
  for	
  research	
  purposes.	

	

	

1.1.2.7.	
  	
  Research	
  on	
  individual	
  or	
  group	
  characteristics	
  or	
  behavior	
  (including,	
  but	
  not	
  limited	
  to,	

research	
  on	
  perception,	
  cognition,	
  motivation,	
  identity,	
  language,	
  communication,	
  cultural	
  beliefs	
  or	

practices,	
  and	
  social	
  behavior)	
  or	
  research	
  employing	
  survey,	
  interview,	
  oral	
  history,	
  focus	
  group,	

program	
  evaluation,	
  human	
  factors	
  evaluation,	
  or	
  quality	
  assurance	
  methodologies.	
  (NOTE:	
  Some

expedited	
  level	
  to	
  the	
  University	
  IRB.	
  	

	

1.2.3	
  	
  Upon	
  receipt	
  of	
  the	
  application	
  form	
  it	
  is	
  entered	
  into	
  the	
  IRB	
  tracking	
  system	
  and	
  assigned	
  an	
  IRB	

number	
  by	
  the	
  IRB	
  Chair	
  or	
  Co-‐Chair.	
  	

	

1.3	
  	
  Pre-‐Review	
  	

1.3.1	
  	
  Research	
  applications	
  submitted	
  by	
  investigators	
  who	
  request	
  expedited	
  review	
  will	
  be	
  evaluated	

by	
  one	
  or	
  more	
  of	
  the	
  PMs,	
  or	
  their	
  designee,	
  who	
  will	
  determine	
  if	
  the	
  project	
  qualifies	
  for	
  expedited	

review.	
  	

	
  	
  	

1.3.2	
  	
  If	
  the	
  protocol	
  does	
  not	
  meet	
  the	
  criteria	
  for	
  expedited	
  review,	
  the	
  PM	
  will	
  change	
  and	
  initial	
  the	

review	
  designation	
  on	
  the	
  application	
  form,	
  which	
  will	
  be	
  processed	
  for	
  review	
  at	
  the	
  appropriate	
  level.	
  	

	

1.3.3	
  	
  The	
  IRB	
  Chair	
  or	
  Co-‐Chair	
  will	
  distribute	
  each	
  application	
  to	
  one	
  or	
  more	
  PM	
  and	
  one	
  or	
  more	

reviewers	
  designated	
  by	
  the	
  Chair	
  from	
  among	
  members	
  of	
  the	
  IRB.	
  	
  Reviewers	
  are	
  assigned	
  based	
  on	

their	
  experience	
  and	
  expertise	
  in	
  the	
  area	
  of	
  research	
  proposed	
  in	
  the	
  application	
  and	
  on	
  any	
  required	

special	
  representation.	
  	
  If	
  no	
  members	
  of	
  the	
  board	
  possess	
  the	
  required	
  expertise,	
  the	
  IRB	
  Chair	
  or	
  Co-‐
Chair	
  will	
  solicit	
  an	
  external	
  reviewer	
  to	
  serve	
  as	
  a	
  consultant	
  to	
  the	
  IRB	
  member	
  reviewing	
  the	

application	
  and	
  the	
  IRB.	

1.3.4	
  	
  The	
  IRB	
  Chair	
  or	
  Co-‐Chair	
  prepares	
  review	
  materials	
  to	
  be	
  distributed	
  to	
  each	
  reviewer.	
  The	

reviewers	
  receives	
  a	
  transmittal	
  email	
  with	
  the	
  desired	
  return	
  date,	
  a	
  complete	
  copy	
  of	
  the	
  application,	

the	
  appropriate	
  IRB	
  Member	
  Review	
  Sheet	
  to	
  document	
  their	
  review	
  and	
  decision	
  regarding	
  approval.	
  	

The	
  reviewers	
  are	
  given	
  seven	
  days	
  to	
  review	
  the	
  application	
  and	
  respond.	

1.4	
  	
  Review	

1.4.1	
  	
  The	
  expedited	
  reviewer	
  exercises	
  all	
  of	
  the	
  authority	
  of	
  the	
  IRB	
  except	
  that	
  the	
  reviewer	
  may	
  not	

disapprove	
  research.	
  The	
  IRB	
  may	
  only	
  disapprove	
  a	
  research	
  application	
  in	
  accord	
  with	
  the	
  non-‐
expedited	
  review	
  procedures	
  set	
  forth	
  in	
  federal	
  regulations	
  45	
  CFR	
  46.108(b).	
  Any	
  one	
  reviewer	
  may	

request	
  review	
  of	
  an	
  application	
  by	
  the	
  IRB	
  at	
  a	
  convened	
  meeting.	
  	

1.4.2	
  	
  The	
  reviewers	
  must	
  return	
  a	
  copy	
  (electronic	
  or	
  hard	
  copy)	
  of	
  the	
  IRB	
  Review	
  Form	
  with	
  their	

approval	
  decision	
  and	
  any	
  comments	
  to	
  the	
  IRB	
  Chair	
  or	
  Co-‐Chair.	

1.5	
  Review	
  Outcomes	

1.5.1	
  	
  The	
  reviewer	
  makes	
  one	
  of	
  the	
  following	
  determinations	
  or	
  recommendations	
  by	
  completing	
  the	

IRB	
  Review	
  form:	
  	

Approved:	
  The	
  research	
  procedures	
  and	
  associated	
  documents	
  meet	
  the	
  criteria	
  for	
  approval	

with	
  no	
  further	
  revision	
  needed.	
  	

Approved	
  with	
  Conditions:	
  The	
  research	
  procedures	
  and	
  associated	
  documents	
  meet	
  the	
  criteria	

for	
  approval	
  with	
  no	
  further	
  revision	
  needed.	
  However,	
  final	
  approval	
  is	
  contingent	
  upon

the	
  research	
  can	
  be	
  approved.	
  The	
  investigator	
  must	
  submit	
  the	
  revisions	
  for	
  review.	

	

Designated	
  for	
  full	
  board	
  revie
w:	
  The	
  reviewer	
  determines	
  that	
  the	
  application	
  should	
  be	

reviewed	
  at	
  a	
  convened	
  meeting	
  of	
  the	
  IRB	
  or	
  via	
  expedited	
  review.	

	

1.5.2	
  The	
  approval	
  period	
  for	
  the	
  application	
  is	
  determined	
  at	
  the	
  time	
  of	
  review.	
  The	
  approval	
  period

Chair	
  via	
  a	
  written	
  document	
  that	
  includes	
  justification	
  for	
  changing	
  the	
  IRB	
  decision.	
  The	
  reviewer	
  and	

the	
  Chair	
  will	
  agree	
  on	
  a	
  final	
  resolution.	
  If	
  the	
  investigator	
  is	
  still	
  dissatisfied	
  with	
  the	
  IRB	
  decision,	
  the	

application	
  will	
  be	
  sent	
  to	
  the	
  convened	
  IRB	
  for	
  review.
	

	

	

1.6

	
  Notification	
  of	
  the	
  IRB	

	

IRB	
  applications	
  that	
  undergo	
  expedited	
  review	
  are	
  documented	
  monthly	
  by	
  the	
  IRB	
  Chair	
  or	
  Co
-‐Chair	

and	
  a	
  list	
  is	
  made	
  available	
  to	
  all	
  members	
  via	
  the	
  IRB	
  email	
  and	
  presented	
  to	
  the	
  Board	
  at	
  the	
  next	

convened	
  meeting.	

	

	

	

2.	
  SCOPE	

	

This	
  procedure	
  applies	
  to	
  research	
  applications	
  submitted	
  for	
  expedited	
  review.	

	

	

3.	
  RESPONSIBILITY	

	

Investigators	
  are	
  responsible	
  for	
  making	
  a	
  preliminary	
  determination	
  that	
  their	
  applications	
  are	
  eligible	

for	
  expedited	
  review.	
  The	
  IRB	
  Chair	
  or	
  Co
-‐