Options appraisal for supporting research studies involving the creation of cell lines from donated material in ODT (Draft)

Three options exist to manage consent for cell lines in ODT;

1) Specific consent
2) Generic consent – with information provided in the research information leaflet
3) ODT do not support research studies that intend to generate cell lines

The anticipated impact of each of these approaches in ODT:

1) Specific consent

ODT will need to consider whether all families are explicitly consented for the potential that studies may generate cell lines – or individual studies are identified and specific consent is taken for the individual study.

Donor Families:
Grieving donor families already receive a significant amount of information at the time of consent for both organ donation and research. A decision to take specific consent for use of donor material to support cell line generation will increase the amount of information and is likely to impact on the donor conversation.
For some families this is without issue, for others, additional information and discussion sometimes involving multiple studies can be overwhelming.

SNODs would need to manage the research conversation and may stop the research consent if the family became distressed or felt that they had given enough. The priority would be not losing consent for organ donation and therefore not every research project may get raised with the family before the conversation concludes.

SNODS:
SNODs are trained to obtain specific consent for each study in their region that requires this. The additional studies should not result in any detrimental impact for the SNOD if they are comfortable with the study content and consent discussions. In some family discussions though, additional multiple specific consents may place further pressure on the SNODs in an already challenging environment. There is significant information which the SNOD needs to be able to recall and discuss with the family at the time of donation. This pressure upon SNODs has been recognised with the INOAR work where there is an attempt to reduce the number of specific consent research studies. Adding additional specific consents counteracts the INOAR work to reduce this. Extra support for the SNOD team to help them with discussion techniques for approaching families for multiple studies or to discuss the animal/DNA/commercial aspects has been requested at a recent ODT Research Lean Event and also in feedback from some teams. Work is ongoing with the

Education Team to provide this; research conversations are now going to be included in the SNOD annual consent training days held with the actor input. Evidence has shown there has been a variation in generic research consent rates throughout the regions coinciding with the implementation of HTA Codes as outlined in Appendix 3. This appears to have improved and further work was undertaken last year to revisit the HTA codes discussion. Further review of ongoing rates is required. There may be similarities seen with the specific research consent rates should there be an increase to these studies and therefore more burden on the families and SNODs. We have seen a variation in consent for specific studies in regions. Work is undergoing to address this directly if required.

Researchers:
This approach would enable the support of proposed studies involving the use of cell lines as NHSBT can ensure that all the relevant information is provided. This approach may also limit the number of ongoing studies each region can support at any one time. Priority for specific studies should be established by RINTAG when there is more than one study competing to be rolled out in the same region or when an active study requests to be extended for a further period and will potentially limit future studies in that region. For historic studies which have to be changed from generic to specific this has a larger impact involving resubmission for REC for revisions of consent documentation and family information leaflets. There would also need to be consideration of what happens whilst these studies are being reviewed and changed.

NHSBT:
There is a reputational risk in asking researchers to change the consent process in a study that was originally approved through generic consent. There is also a reputational risk for NHSBT to leave this unresolved.
It should be noted that within NHSBT other directorates take specific consent for studies involving the creation of cell lines from donated material (e.g. blood donors).

INOAR:
It should be acknowledged that taking specific consent for the purposes of studies involving cell lines is contradictory to the current work of NHSBT surrounding INOAR which is promoted to reduce the number of specific studies requiring consent.

INOAR will bring about changes to the consent process and there is a working group reviewing the impact. Any decision of consent requirements for cell lines would need to be considered as part of this work.

2) Generic Consent

Future studies will be approved to the agreed standard through generic consent. The historic studies have been approved by a Research Ethics Committee to be undertaken with material gained via generic consent

Families:

Information could be provided in the Research Information Leaflet (INF1167). This would require changes to the current Information leaflet which would incorporate the essential cell line information to be shared with families. The possible use of cell lines could be highlighted to families at the same time as the commercial, DNA and animal testing studies are raised. This approach would allow the opportunity for families to restrict research consent in line with the HTA codes of practice. It also gives the family the opportunity to withdraw research consent, up to the point of sample use, should they re-consider post donation. NHSBT may wish to consider whether the level of information to be provided would be achievable in an information leaflet. This would be agreed by RINTAG. This proportionate approach is currently supported by the HTA and any changes to the Research Information Leaflet (INF1167) would be in addition to the current agreed requirements.

SNODS:
This approach is in line with current practice and would not be a significant operational change. Additional information relating to the use of cell lines could be included on INF1374 to support the SNOD's knowledge base. This approach would require minimal change to the current process. ODT Hub Operations are already using this process and would therefore require minimal operational change.

Researchers:
For the research teams this approach allows the support of studies involving the use of cell lines with the reassurance that this approach is acceptable to the HTA. A mechanism is already in place to identify any studies with DNA, commercial or animal implications to ensure family research restrictions are upheld. Studies involving the use of cell lines can be incorporated into this to ensure that if the family wish to restrict donations into certain types of studies, this can be upheld. Researchers are now asked to provide information regarding animal, DNA, Commercial aspects of their studies. Cell lines can be added to the application form. The researcher's MOU is being updated to include a limitation on passing any material to a third party without NHSBT knowledge and permission to provide robust governance.

NHSBT:
Would need to ensure that families are provided with enough information via the generic route to ensure informed consent and that ethical requirements are satisfied.

INOAR:
These studies will access declined organs and those organs removed for the purposes of research under generic consent. They will also be able to access organs gained via INOAR.

3) **NHSBT does not support studies which involve the use of cell lines.**

NHSBT do not support research studies which involve the use of cell lines.

Families:

Removing the need to approach for studies involving cell lines would remove any additional burden to the donor family. This would also remove the risk of families

consenting without knowing the potential outcome of donating organs to a research study involving the use of cell lines. **However, this approach** could potentially deny families the opportunity to participate in such studies.

SNODs:
This approach removes the need for any additional training or the need to obtain consent for the use of studies involving cell lines.

Researchers:
For the research teams this approach would result in the denial of access to organs for research in studies involving the use of cell lines. Studies with existing NHSBT approval would need to cease.

NHSBT:
This would restrict our ability to support research requiring the generation of cell lines, however, many researchers access material from sources other than donors consented by NHSBT to produce cell lines.

INOAR:
A number of studies would be removed from the database and the requirement for organs for research may reduce.