Nagħti l-kunsens tiegħi.

**(L.S.)** GEORGE ABELA
President

4 ta’ Diċembru, 2012

# ATT Nru. XXI tal-2012

*ATT sabiex jipprovdi protezzjoni għal embrijuni umani u materji anċillari oħra*

IL-PRESIDENT, bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqa’ f’dan il-Parlament, u bl-awtorità tal-istess, ħareġ b’liġi dan li ġej:-

**1**. (1) It-titolu fil-qosor ta’ dan l-Att huwa l-Att tal-2012 dwar il-Protezzjoni ta’ Embrijuni. Titolu fil-qosor u bidu fis-seħħ.

(2) Dan l-Att għandu jidħol fis-seħħ fil-jum li l-Ministru responsabbli għall-ġustizzja flimkien mal-Ministru responsabbli għas-saħħa, jistabbilixxi b’avviż fil-Gazzetta, u dati differenti jistgħu jiġu stabbiliti għal skopijiet u dispożizzjonijiet differenti ta’ dan l-Att.

**2.** F’dan l-Att sakemm ir-rabta tal-kliem ma teħtieġx xort’ oħra:- Tifsir.

"l-Awtorità" tfisser l-Awtorità għall-Protezzjoni ta’ Embrijuni stabbilit bl-artikolu 3;

"ċelloli *germ line*" tfisser iċ-ċelloli tal-bajd u tal-isperma kollha li jistgħu jwasslu biex jinħoloq bniedem;

"Direttiva" tfisser id-Direttiva 2004/23/KE tal-Parlament Ewropew u tal-Kunsill tal-31 ta’ Marzu, 2004 fuq l-għemil ta’ livelli dwar il-kwalità u s-sigurezza għad-donazzjoni, ksib, ittestjar, ipproċessar, preservazzjoni, ħżin u distribuzzjoni ta’ tessut u ċelloli

uman;

"embrijun" tfisser l-organiżmu uman li jirriżulta mill-fertilizzazzjoni ta' ċellola tal-bajd umana minn ċellola tal-isperma umana li tkun kapaċi tiżviluppa u għandha wkoll tinkludi kull ċellola totipotenti mneħħija minn embrijun uman jew prodott mod ieħor, li hija preżunta li tista' tiddividi ruħha u tiżviluppa bħala bniedem uman taħt il-kundizzjonijiet xierqa;

"ġenitur prospettiv" tfisser wieħed jew waħda minn żewġ persuni tas-sess oppost li huma marbutin bir-rabta taż-żwieġ, jew li jkunu laħqu l-età maġġuri u li huma f'relazzjoni stabbli ma' xulxin.

"il-Kunsill" tfisser il-Kunsill Mediku imwaqqaf bl-artikolu 9 tal-Att dwar il-Professjonijiet tas-Saħħa;

Kap. 464.

"Ministru" tfisser il-Ministru responsabbli għas-saħħa;

"professjonist fil-kura medika" għandha l-istess tifsira mogħtija lilha bl-artikolu 2 tal-Att dwar il-Professjonijiet tas-Saħħa;

Kap. 464.

"prokreazzjoni assistita b'mod mediku" tfisser dak il-proċess li bih embrijun jiżviluppa wara t-tlaqqigħ tal-gamiti, liema proċess ikun ġie megħjun b'mezzi li jmorru lil hinn mill-proċess naturali waħdu u li jinkludu kull intervent fil-ġisem jew barra mill-ġisem li jgħin it-tlaqqigħ tal-gamiti u t-tpoġġija tagħhom, jew tal-embrijun li jista' jiżviluppa minn dan it-tlaqqigħ, fis-sistema riproduttiva tal-mara;

"tabib" tfisser persuna liċenzjata skont l-Att dwar il-Professjonijiet tas-Saħħa sabiex jipprattika bħala tabib;

Kap. 464.

Twaqqif u għamla tal-Awtorità għall-Protezzjoni ta' Embrijuni.

**3.** (1) Għandu jkun hemm korp, li jkun magħruf bħala l-Awtorità għall-Protezzjoni ta' Embrijuni, li jkun magħmul minn *Chairman* u numru ta' membri li ma jkunx anqas minn erba', maħtura mill-Ministru.

(2) Iċ-*Chairman* għandu jkun persuna li jkollha *warrant* biex teżerċita l-professjoni ta' Avukat u illi tkun eżerċitat dik il-professjoni għal perjodu ta' mill-anqas tnax-il sena jew Imħallef irtirat jew Maġistrat irtirat.

(3) Persuna ma tkunx kwalifikata li jkollha l-kariga ta' membru tal-Awtorità jekk:

(a) tkun Ministru jew Segretarju Parlamentari;

(b) tkun membru tal-, jew kandidat għall-elezzjoni għall-Kamra; jew

(ċ) tkun membru ta' awtorità tal-gvern lokali; jew

(d) għandha interess finanzjarju jew interess ieħor f'xi intrapriża jew attività li x'aktarx taffettwa t-twettiq tal-funzjonijiet tagħha bħala membru tal-Awtorità.

(4) Bla ħsara għad-dispożizzjonijiet ta' dan l-artikolu, il-kariga ta' membru tal-Awtorità ssir vakanti -

(a) meta jiskadi ż-żmien ta' ħames snin mid-data tal-ħatra tiegħu jew f'dik id-data li tiġi qabel skont ma jista' jiġi speċifikat fl-istrument li bih ikun inħatar; jew

(b) meta tinqala' xi ċirkostanza li, kieku persuna ma kienetx membru tal-Awtorità, kienet iġġib l-iskwalifika tagħha għal dik il-ħatra.

(5) Membru tal-Awtorità jista' jitneħħa mill-kariga mill-Ministru jekk, fil-fehma tal-Ministru, dak il-membru ma jkunx idoneu biex ikompli f'dik il-kariga jew ikun sar inkapaċi milli jwettaq kif imiss dmirijietu bħala membru, kemm jekk minħabba f'nuqqas ta' saħħa tal-moħħ jew tal-ġisem jew għal xi raġuni oħra, jew minħabba f'imġieba ħażina.

(6) Jekk il-kariga ta' membru tal-Awtorità issir vakanti jew membru jkun għal xi raġuni inkapaċi li jwettaq il-funzjonijiet tal-kariga tiegħu, il-Ministru jista' jaħtar persuna oħra bħala membru temporanju tal-Awtorità sakemm il-membru li ma setgħax iwettaq il-funzjonijiet tal-kariga tiegħu jerġa jidħol f'dik il-kariga.

(7) Il-membri tal-Awtorità, fit-twettiq tal-funzjonijiet tagħhom għandhom jaġixxu fuq il-ġudizzju individwali tagħhom u m'għandhomx ikunu suġġetti għad-direzzjoni jew kontroll ta' xi persuna jew awtorità.

Funzjonijiet u setgħat tal-Awtorità.

**4.** (1) Il-funzjonijiet u s-setgħat tal-Awtorità għandhom ikunu li ġejjin:

(a) li tiżgura li tobba, paramediċi u kull persunal ieħor involut fi proċeduri ta' prokreazzjoni assistita b'mod mediku jżommu *standards* għoljin ta' etika;

(b) li fejn jeżisti suspett raġonevoli illi d-dispożizzjonijiet ta' dan l-Att mhumiex qed jiġu mħarsa, titlob u tottjeni informazzjoni u kopji, f'kull forma, ta' dokumenti meħtieġa skont id-Direttiva sabiex ikunu rintraċċati ċelloli umani;

(ċ) li twettaq spezzjonijiet sabiex tiżgura illi l-i*standards* tal-aħjar prattika qegħdin jiġu rispettati u applikati u illi kull informazzjoni u dokumentazzjoni meħtieġa skont l-artikolu 18 tkun qiegħda tinżamm kif jixraq u għal dan il-għan li taċċedi fi kliniċi u f'kull postijiet oħra hekk kif meħtieġ;

(d) li żżomm rendikont ta' prinċipji ġenerali liema, fl-opinjoni tagħha, għandhom jiġu segwiti:

(i) fit-twettiq tal-attivitajiet tagħha taħt dan l-Att; u

(ii) fit-twettiq tal-funzjonijiet tagħha fir-rigward ta' dawk l-attivitajiet taħt dan l-Att;

(e) li tiżgura, fir-rigward tal-attivitajiet taħt dan l-Att, konformità ma:

(i) l-obbligi u l-ħtiġiet imposti bi jew taħt dan l-Att; u

(ii) il-kodiċijiet ta' prattika stabbiliti taħt il-paragrafu (a);

(f) li twettaq dawk il-funzjonijiet oħra kif jistgħu, minn żmien għal żmien, jiġu preskritti b'regolamenti taħt dan l-Att.

(2) Minkejja d-dispożizzjonijiet tal-artikolu 7, iżda mingħajr ħsara għad-dispożizzjonijiet tal-artikolu 18, l-Awtorità tista' tagħti għal adozzjoni ċelloli tal-bajd fertilizzati, fil-każ meta, wara li ssir il-fertilizzazzjoni taċ-ċelloli tal-bajd iżda qabel ma ssir l-impjantazzjoni tal-embrijuni fil-ġuf, tmut il-mara jew fil-każ meta għal xi raġuni oħra, dik l-impjantazzjoni ma tistax issir.

(3) Ebda ħaġa f'dan l-artikolu ma għandha tippreġudika l-awtorità jew l-eżerċizzju ta' xi funzjoni jew setgħa tal-Awtorità dwar
Kap. 483. il-Liċenzi taħt l-Att dwar id-Demm Uman u Trapjanti:

Iżda matul il-perjodu mid-data tal-ġurnata li fiha l-impjantazzjoni ma setgħetx issir aktar għar-raġuni jew raġunijiet preċitati sad-data tal-għoti għall-adozzjoni, jekk issir, l-Awtorità għandha titqies bħala kuratriċi tal-embrijun għall-finijiet u l-effetti kollha tal-liġi u l-Awtorità għandha minnufih u matul iż-żmien kollu tal-kurazija tinforma u tikkonsulta lill-ġenitur jew ġenituri prospettivi, u fin-nuqqas ta' dawn lill-eredi legali tagħhom, dwar id-deċiżjonijiet li għandhom jittieħdu dwar l-embrijun. B'dana li f'każ li ż-żewġ ġenituri prospettivi jistgħu jkunu konsultati, l-Awtorità għandha safejn hu possibbli tirrispetta x-xewqa tal-ġenituri fil-

paramentri ta' dan l-Att:

Iżda l-ġenitur jew ġenituri prospettivi, u fin-nuqqas ta' dawn l-eredi legali tagħhom, jista' fi żmien għoxrin ġurnata mid-data tad-deċiżjoni tal-Awtorità għall-għoti taċ-ċellola tal-bajd fertilizzat għall-adozzjoni jitlob lill-Qorti Ċivili (Sezzjoni tal-Familja) b'rikors ġuramentat biex tiddeċiedi fl-interess suprem tal-embrijun favur min dan l-embrijun għandu jingħata għall-adozzjoni.

Dritt għal proċeduri ta' prokreazzjoni assistita b'mod mediku.

**5.** (1) Kull ġenitur prospettiv għandu jkollu aċċess għal proċeduri ta' prokreazzjoni assistita b'mod mediku:

Iżda dawn il-proċeduri jista' jsir użu minnhom biss fejn ikun hemm iċ-ċans raġonevoli ta' suċċess u li l-proċeduri ma jkunux jinvolvu xi riskju magħruf bla bżonn lis-saħħa tal-mara jew tat-tfal, apparti dawk ir-riskji diġà magħrufa tajjeb bħala marbuta b'mod inerenti ma' din il-proċedura.

(2) Kull persuna li tipprovdi, jew tassisti fi, xi proċedura ta' prokreazzjoni assistita b'mod mediku lil persuna oħra li ma tkunx il-ġenitur prospettiv, tkun ħatja ta' reat u teħel multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn tlieta u għoxrin elf euro (€23,000) jew priġunerija ta' mhux aktar minn ħames snin jew dik il-multa u l-priġunerija flimkien:

Iżda meta l-persuna tkun tabib li jkun wettaq l-imsemmija proċedura, it-tabib għandu jiġi eżentat mir-responsabbilità kriminali meta juri li jkun ta attenzjoni raġonevoli biex jiddetermina li, l-persuna li fuqha twettqet il-proċedura jew kien hemm tentattiv biex titwettaq, kienet intitolata għal aċċess għal proċedura bħal dik.

Proċeduri illegali.

**6.** Kull min –

(a) jiffertilizza b'mod artifiċjali xi ċellola tal-bajd għal kull skop ħlief dak sabiex tiġi t-tqala tal-mara minn fejn oriġinat iċ-ċellula;

(b) intenzjonalment jiffertilizza aktar minn żewġ ċelloli tal-bajd minn mara waħda f'ċiklu ta' trattament wieħed:

Iżda f'każijiet eċċezzjonali t-tabib inkarigat mill-proċedura ta' prokreazzjoni assistita jista' jiddeċiedi li jittrasferixxi sa massimu ta' tliet ċelloli tal-bajd fertilizzati f'mara f'ċiklu ta' trattament wieħed sakemm dan isir skont protokoll stabbilit bil-miktub mill-Awtorità wara konsultazzjoni mal-assoċjazzjonijiet rikonoxxuti b'liġi li jirrappreżentaw lit-tobba fl-oqsma tal-obstetrija u pedjatrija. Dan il-Protokoll għandu jinkludi, mingħajr ħsara għal kriterji oħra, kriterji ċari

rigward l-età tal-mara li se tipparteċipa fil-proċedura u wara kemm-il ċiklu ta' trattament skont paragrafu (b) jista' t-tabib inkarigat jiddeċiedi li jiffertilizza sa massimu ta' tliet ċelloli tal-bajd:

Iżda wkoll dan il-Protokoll imsemmi hawn fuq jista' jkun sostitwit bi Protokoll stabbilit bi qbil mal-assoċjazzjonijiet rikonoxxuti b'liġi li jirrappreżentaw lit-tobba fl-oqsma tal-obstetrija u pedjatrija, u li jispeċifika b'mod dettaljat l-aħjar proċedura medika fil-qasam tal-prokreazzjoni assistita b'mod mediku. Jekk ma jintlaħaqx qbil bejn l-Awtorità u l-assoċjazzjonijiet fuq dan il-Protokoll, il-Protokoll stabbilit bil-miktub mill-Awtorità taħt l-ewwel proviso, għandu japplika:

Iżda wkoll kopji awtentikati ta' dan il-Protokoll għandhom jintbagħtu fi żmien jumejn lill-Ministru responsabbli għas-Saħħa u lill-iSpeaker tal-Kamra tad-Deputati. L-iSpeaker tal-Kamra tad-Deputati, jew fin-nuqqas tiegħu d-Deputat Speaker, għandu jqiegħed il-kopja awtentikata tal-Protokoll fuq il-Medja tal-Kamra fl-ewwel seduta Parlamentari li jkun imiss mill-mument li jkun irċieva dan id-dokument:

Iżda wkoll meta l-persuna tkun tabib, ebda passi kriminali ma jistgħu jittieħdu kontra t-tabib jekk it-tabib ikun qiegħed jaġixxi fedelment u *bona fide* skont il-Protokoll imsemmi hawn fuq.

(ċ) ma jittrasferixxix l-embrijuni kollha prodotti f'mara f'ċiklu ta' trattament wieħed;

(d) ineħħi embrijun minn mara qabel ma titlesta l-impjantazzjoni fil-ġuf sabiex jiġi trasferit f'mara oħra l-embrijun;

(e) jagħżel jew iwarrab embrijun għal finijiet ewġeniċi;

(f) iwettaq fertilizzazzjoni b'mod artifiċjali ta', jew jittrasferixxi embrijun uman fi, mara li tkun ippreparata li ċċedi b'mod permanenti t-tifel jew it-tifla tagħha wara li jitwieled jew titwieled (omm surrogata),

tkun ħatja ta' reat u teħel multa ta' mhux anqas minn ħamest elef euro (€5,000) u mhux aktar minn ħmistax-il elf euro (€15,000) jew priġunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-priġunerija flimkien:

Iżda -

(i) il-mara li minnha jkunu oriġinaw iċ-ċellola tal-bajd jew l-embrijun, fir-rigward tal-aġir imsemmi fil-paragrafi (a) u (d); u, jew

(ii) il-mara li fiha ser jiġu trasferiti ċ-ċellola tal-bajd jew l-embrijun, fir-rigward tal-aġir imsemmi fil-paragrafu (f);

ikollha tnaqqis fil-piena b'grad wieħed jew tnejn.

Projbizzjoni ta' preservazzjoni ta' embrijuni.

**7.** Kull forma ta' preservazzjoni, inkluż il-krijo-preservazzjoni ta' embrijuni, hija projbita u kull min jikser xi dispożizzjoni ta' dan l-artikolu ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn ħamest elef euro (€5,000) u mhux aktar minn ħmistax-il elf euro (€15,000) jew priġunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-priġunerija flimkien:

Iżda meta t-trasferiment fil-ġuf tal-embrijun fertilizzat ma jkunx possibbli minħabba forza maġġuri gravi u ppruvata li ma tkunx ġiet preveduta fil-mument tal-fertilizzazzjoni, dawn l-embrijuni jistgħu jiġu preservati sad-data ta' dak it-trasferiment liema trasferiment għandu jsir mill-aktar fis posibbli:

Iżda wkoll meta jsir xi ksur ta' xi dispożizzjoni ta' dan l-Att, l-Awtorità tista' tordna l-iffriżar ta' xi embrijun sabiex tiġi preservata l-ħajja tiegħu.

Użu mhux xieraq ta' embrijuni umani.

**8.** (1) Kull min, barra mill-finijiet ta' implantazzjoni f'mara kif hekk awtorizzat bid-dispożizzjonijiet ta' dan l-Att, jiddisponi minn, jgħaddi lil jew jikseb embrijun uman prodott barra mill-ġisem, jew ineħħi dak l-embrijun minn mara qabel ma titlesta l-impjantazzjoni fil-ġuf, ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn ħamest elef euro (€5,000) u mhux aktar minn ħmistax-il elf euro (€15,000) jew priġunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-priġunerija flimkien.

(2) Kull min jikkawża li jiġi żviluppat embrijun uman barra mill-ġisem għal finijiet barra minn dawk sabiex tiġi t-tqala, ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn ħamest elef euro (€5,000) u mhux aktar minn ħmistax-il elf euro (€15,000) jew priġunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-priġunerija flimkien.

Użu mhux xieraq eċċ, ta' gameti.

**9.** L-użu, it-trasferiment u l-fertilizzazzjoni ta' xi ċelloli *germ line* li ma jkunux oriġinaw mill-ġenitur prospettiv huma projbiti u kull persuna, li tikser xi dispożizzjoni ta' dan l-artikolu tkun ħatja ta' reat u teħel multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn tlieta u għoxrin elf euro (€23,000) jew priġunerija

ta' mhux aktar minn ħames snin jew dik il-multa u l-priġunerija flimkien:

Iżda meta l-persuna tkun tabib, dan għandu jiġi eżentat mir-responsabbilità kriminali meta juri li jkun ta attenzjoni raġonevoli biex jiddetermina li l-persuna li minnha oriġinaw iċ-ċelloli *germ line* kienet ġenitur prospettiv skont it-tifsira ta' dan l-Att.

Projbizzjoni ta' għażla ta' sess.

**10.** (1) Kull persuna li tiffertilizza b'mod artifiċjali ċellola tal-bajd umana ma ċellola tal-isperma li tkun intgħażlet għal-kromosoma ta' sess li tkun fiha, tkun ħatja ta' reat u teħel multa ta' mhux anqas minn erbat elef euro (€4,000) u mhux aktar minn għaxart elef euro (€10,000).

(2) Ebda ħaġa li tinsab fis-subartikolu (1) ma għandha tinftiehem li tipprevjeni s-selezzjoni ta' ċellola tal-isperma minn tabib sabiex jiġi prevenut it-tifel jew it-tifla milli jimrad/timrad minn marda ġenetika li għandha x'taqsam mas-sess.

Projbizzjoni ta' proċess ta' *cloning*.

**11.** (1) Kull intervent, intenzjonat sabiex jinħoloq bniedem ġenetikament identiku ma' embrijun ieħor, *foetus,* jew bniedem, kemm ħaj jew mejjet, huwa projbit u għal finijiet ta' dan l-artikolu l-kliem "ġenetikament identiku" jfissru bniedem li jaqsam ma' ieħor l-istess sett ta' ġene nukleari.

(2) Kull min jintervjeni jew jipparteċipa f'xi intervent artifiċjali kif imsemmi fis-subartikolu (1) jkun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn tlieta u għoxrin elf euro (€23,000) jew priġunerija ta' mhux aktar minn ħames snin jew dik il-multa u l-priġunerija flimkien.

(3) Kull min jittrasferixxi embrijun f'mara kif imsemmi fis-subartikolu (1) jeħel l-istess piena stabbilita fis-subartikolu (2).

Fertilizzazzjoni, trasferiment ta' embrijun u fertilizzazzjoni artifiċjali mhux awtorizzat wara l-mewt.

**12.** (1) Kull min -

(a) jiffertilizza b'mod artifiċjali ċellola tal-bajd mingħajr il-kunsens tal-mara, liema ċellola tal-bajd ser tiġi fertilizzata, jew mingħajr il-kunsens tar-raġel, liema ċellola tal-isperma ser tintuża għall-fertilizzazzjoni;

(b) jittrasferixxi embrijun f'mara mingħajr il-kunsens tagħha;

(ċ) xjentement jiffertilizza b'mod artifiċjali ċellola tal-bajd mal-isperma tar-raġel wara mewtu;

(d) xjentement jiffertilizza b'mod artifiċjali ċellola tal-bajd tal-mara wara mewtha;

jkun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn ħamsa u għoxrin elf euro (€25,000):

Iżda l-piena tiġi mnaqqsa b'grad wieħed jew żewġ gradi -

(i) fir-rigward tal-mara li l-bajda tagħha ġiet iffertilizzata, fir-rigward tal-paragrafu (ċ); u

(ii) fir-rigward tar-raġel li l-isperma tiegħu intużat għal fertilizzazzjoni, fir-rigward tal-paragrafu (d).

(2) Xejn f'dan l-Att m'għandu jiġi interpretat li jimpedixxi għal raġunijiet mediċi u skont normi mediċi aċċettati t-teħid u l-iffriżar tal-isperma jew tal-bajda ta' persuna bl-iskop ta' użu tal-istess sperma jew bajda fi stadju ulterjuri mill-istess persuna li minnha ġiet meħuda jew iffriżata l-isperma jew il-bajda biex flimkien ma' persuna oħra tas-sess oppost jiġi ġġenerat embrijun:

Iżda xejn f'dan l-Att m'għandu jinftiehem li qed jippermetti f'xi stadju t-trasferiment u, jew id-donazzjoni ta' ċelloli tal-bajda umana u, jew ċelloli tal-isperma umana.

Projbizzjoni ta' tibdil artifiċjali ta' ċelloli *germ line* tal-bnedmin.

**13.** (1) Mingħajr ħsara għad-dispożizzjonijiet tas-subartikolu (3), kull min xjentement jibdel b'mod artifiċjali l-informazzjoni ġenetika ta' ċellola *germ line* umana, ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn tlieta u għoxrin elf euro (€23,000) jew priġunerija ta' mhux aktar minn ħames snin jew dik il-multa u l-priġunerija flimkien.

(2) Kull min xjentement juża ċellola *germ line* uman ma informazzjoni ġenetika mibdula b'mod artifiċjali għal fertilizzazzjoni ikun ħati ta' reat u jeħel l-istess piena stabbilita fis-subartikolu (1).

(3) L-ebda reat ma jiġi kommess mit-tabib li jkun wettaq il-proċedura assistita b'mod mediku, taħt is-subartikolu (1) fejn it-tibdil tal-informazzjoni ġenetika taċ-ċellola *germ line* ikun il-konsegwenza mhux intenzjonata, ta' tilqim, radjazzjoni jew trattament jew kimoterpija.

Projbizzjoni ta' formazzjoni ta' *chimerae* u ibridi.

**14.** (1) Kull min -

(a) jgħaqqad embrijuni ma' materjal ġenetiku differenti ma' ċellola konglomerata bl-użu ta' mill-anqas embrijun uman

wieħed; jew

(b) jgħaqqad embrijun uman ma' ċellola li jkun fiha informazzjoni ġenetika differenti miċ-ċelloli ta' embrijun u jikkaġuna li jiġu żviluppati aktar; jew

(ċ) jiffertilizza ċellola tal-bajd umana mal-isperma ta' annimal jew jiffertilizza ċellola tal-bajd ta' annimal mal-isperma ta' raġel, bl-intenzjoni sabiex jiġi ġġenerat embrijun li jkun kapaċi jiżviluppa,

jkun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn sebgħin elf euro (€70,000) jew priġunerija ta' mhux aktar minn seba' snin jew dik il-multa u l-priġunerija flimkien.

(2) Kull min jittrasferixxi f'mara jew f'annimal embrijun li jkun ġie prodott minn proċedura imsemmija fis-subartikolu (1) jew jittrasferixxi f'annimal embrijun uman ikun ħati ta' reat u jeħel l-istess piena stabbilita fis-subartikolu (1).

Projbizzjoni ta' esperimenti fuq embrijuni umani.

**15.** (1) Huwa pprojbit li jsir xi esperiment fuq embrijuni umani u minn jikser id-dispożizzjonijiet ta' dan is-subartikolu jkun ħati ta' reat u jeħel multa ta' mhux anqas minn għaxart elef euro (€10,000) u mhux aktar minn sebgħin elf euro (€70,000) jew priġunerija ta' mhux aktar minn seba' snin jew dik il-multa u l-priġunerija flimkien.

(2) Il-ħolqien ta' embrijuni umani, għall-finijiet ta' riċerka u esperimenti jew għal xi għan ieħor mhux permess taħt dan l-Att, huwa pprojbit u kull min jikser id-dispożizzjonijiet ta' dan is-subartikolu jkun ħati ta' reat u jeħel l-istess piena stabbilita fis-subartikolu (1).

(3) Interventi kliniki fuq embrijun uman huma permessi bil-kondizzjoni illi dawn l-interventi jsiru b'mod eskussiv għal finijiet ta' dijanjosi jew għal finijiet terapewtiċi li huma relatati mal-embrijun u li jsiru għall-interess tas-saħħa u tal-iżvilupp tal-embrijun innifsu:

Iżda ma jkunx disponibbli l-ebda metodu jew proċedura medika alternattiva oħra u l-kunsens bil-miktub tal-ġenituri prospettivi tkun ġiet mogħtija u m'hemm l-ebda riskju bla bżonn għall-embrijun u għall-omm.

Il-kaġun b'mod intenzjonali tal-mewt ta' embrijuni.

**16.** (1) Kull min b'mod intenzjonali jikkaġuna l-mewt ta' xi embrijun ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux aktar minn tnax-il elf euro (€12,000) jew priġunerija ta' mhux aktar minn sentejn jew dik il-multa u l-priġunerija flimkien.

(2) Dan l-artikolu għandu japplika għal xi *cloning* uman maħluq bi ksur tad-dispożizzjonijiet tal-artikolu 11.

17. Id-dispożizzjonijiet tal-artikoli 121D u 248E(4) tal-Kodiċi Kriminali għandhom *mutatis mutandis* japplikaw għal persuna li tkun instabet ħatja taħt dan l-Att.

Applikazzjoni tal-artikoli 121D u 248E(3) tal-Kodiċi Kriminali. Kap. 9.

**18.** (1) Il-kunsens taż-żewġ ġenituri prospettivi li jkun ser ikollhom aċċess għal proċeduri ta' prokreazzjoni assistita b'mod mediku għandu jingħata b'mod espress konġunt fuq dik il-formula, kif tista' tiġi preskritta b'regolamenti taħt dan l-Att, lill-, u fil-preżenza tat-tabib inkarigat mill-proċedura:

Kunsens informat.

Iżda dan il-kunsens jista' jiġi irtirat biss bil-miktub minn wieħed jew waħda mill-ġenituri prospettivi qabel ma jsir il-proċess ta' fertilizzazzjoni.

(2) Għall-finijiet ta' kunsens informat u qabel ma tiġi applikata xi proċedura li twassal għall-prokreazzjoni assistita b'mod mediku, it-tabib inkarigat mill-proċedura għandu jinforma fid-dettal u bil-miktub liż-żewġ ġenituri prospettivi rigward:

(a) il-metodi u trattament ta' kull proċedura li jkunu ser jintużaw;

(b) il-kumplikazzjonijiet li jistgħu jinqagħlu lill-mara u lit-tfal prospettivi;

(ċ) il-probabilità ta' ċans ta' suċċess tal-imsemmija proċedura:

(d) kull riskju involut liż-żewġ ġenituri prospettivi u lit-tfal;

(e) il-possibilità ta' effetti psikoloġiċi bħala riżultat tal-applikazzjoni tal-imsemmija proċedura liż-żewġ ġenituri prospettivi u lit-tfal;

(f) il-kwistjonijiet bioetiċi, inklużi l-proċess tal-iffriżar involut kif imsemmi fl-artikolu 4(2); u

(g) fejn applikabbli, l-ispejjeż tal-proċedura kollha.

(3) It-tabib inkarigat mill-proċedura għandu jiżgura li l-ġenituri prospettivi jirċievu rispettivament pariri kliniċi indipendenti kemm qabel, matul u wara l-proċedura.

(4) Kull tabib responsabbli minn proċedura ta' prokreazzjoni assistita għandu jassigura li tinżamm kopja tad-dokumentazzjoni kollha meħtieġa taħt dan l-Att, inkluż dik id-dokumentazzjoni li tiċċertifika li l-kunsens infurmat rikjest b'dan l-artikolu ingħata wara li l-istess tabib ta l-informazzjoni kollha lill-ġenituri prospettivi u wara li jkun assigura li l-ġenituri prospettivi rċevew il-pariri meħtieġa.

L-istatus tat-tfal imwielda.

**19.** It-tfal li jkunu imwielda minn riżultat ta' proċedura ta' prokreazzjoni assistita b'mod mediku għandhom jiġu kunsidrati bħala t-tfal tal-ġenituri prospettivi li kienu taw il-kunsens tagħhom b'mod espress bil-miktub kif provdut fl-artikolu 18 u dawn it-tfal għandhom, għall-għanijiet u l-finijiet tal-liġi, jiġu kkunsidrati li twieldu b'mod naturali mill-istess ġenituri prospettivi mingħajr l-intervent tal-proċedura kif imsemmija qabel; u bla ħsara għad-dispożizzjonijiet ta' xi liġi oħra, dawn it-tfal għandhom jiġu reġistrati f'kull att ta' stat ċivili bħala dixxendenti diretti ta' dawn il-ġenituri prospettivi li għandhom igawdu dawk id-drittijiet u jassumu dawk l-obbligi skont il-liġi fir-rigward ta' dawn it-tfal.

Oġġezzjoni tal-kuxjenza.

**20.** (1) Professjonist fil-kura medika ma huwa taħt l-ebda obbligu biex jippparteċipa f'xi proċedura sabiex tiġi applikata xi teknika ta' prokreazzjoni assistita b'mod mediku regolata b'dan l-Att, meta dan il-professjonist iqis din il-parteċipazzjoni oġġezzjonabbli bħala kwistjoni ta' kuxjenza u jiddikjara din l-oġġezzjoni min qabel. Din id-dikjarazzjoni għandha tintbagħat, fi żmien tliet xhur mid-data ta' meta dan l-Att jiġi fis-seħħ, lill-Awtorità u lid-direttur tal-isptar jew l-istabbiliment mediku fejn jaħdem il-professjonist fil-kura medika.

(2) L-oġġezzjoni dikjarata kif provdut fis-subartikolu (1) tista' tiġi revokata jew l-imsemmija oġġezzjoni tista' tiġi dikjarata wkoll wara li jkun skada l-perijodu msemmi fis-subartikolu (1), iżda f'dan il-każ id-dikjarazzjoni li tkun qed tqajjem l-oġġezzjoni għandha tiġi fis-seħħ wara li jkun għadda xahar mid-data ta' meta ġiet komunikata kif provdut fis-subartikolu (1).

(3) Din l-oġġezzjoni dikjarata kif imsemmi fis-subartikoli (1) jew (2) għandha jkollha effett sabiex teżenta lill-professjonist fil-kura medika li jkun qed jagħmel id-dikjarazzjoni milli jipparteċipa f'xi proċedura jew f'attività speċifikatament jew neċessarjament intiża għall-implimentazzjoni tat-teknika jew proċedura li twassal għall-prokreazzjoni assistita b'mod mediku iżda ma teżentahx milli jipprovdi għajnuna qabel jew wara l-imsemmija proċedura jew attività.

**21.** Mingħajr ħsara għal kull piena preskritta b'dan l-Att jew b'xi liġi oħra, meta il-persuna li tinstab ħatja ta' reat taħt dan l-Att huwa tabib jew professjonist fil-kura medika, il-Qorti għandha tordna li tintbagħat kopja tas-sentenza lill-kunsill kompetenti taħt l-Att dwar il-Professjonijiet tas-Saħħa u lill-Ministru. Pieni addizzjonali. Kap. 464.

**22.** Ebda post ma jista' jintuża għal xi attività li jkollha x'taqsam ma' prokreazzjoni assistita b'mod mediku sakemm dak il-post ma jkunx liċenzjat għaldaqstant mill-Awtorità dwar il-Liċenzi skont l-Att dwar id-Demm Uman u Trapjanti u kull regolamenti magħmula taħtu. Liċenza tal-post. Kap. 483.

**23.** Il-Ministru jista', flimkien mal-Ministru responsabbli għall-ġustizzja, jagħmel regolamenti sabiex: Setgħa biex isiru regolamenti.

(a) jippreskrivi dak kollu li jista' jiġi preskritt għall-implimentazzjoni u l-eżekuzzjoni tad-dispożizzjonijiet ta' dan l-Att;

(b) jirregola l-liċenzar ta' postijiet użati sabiex jitwettqu proċeduri ta' prokreazzjoni assistita b'mod mediku inklużi l-kondizzjonijiet meħtieġa għal tabib biex jipprattika xi proċedura bħal din f'postijiet bħal dawn;

(ċ) jistipula kondizzjonijiet sabiex jitwettqu dawn il-proċeduri ta' prokreazzjoni assistita b'mod mediku.

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Mgħoddi mill-Kamra tad-Deputati fis-Seduta Nru. 528 tas-26 ta' Novembru, 2012.

MICHAEL FRENDO
*Speaker*

RAYMOND SCICLUNA
*Skrivan tal-Kamra tad-Deputati*

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I assent.

**(L.S.)** GEORGE ABELA
President

4th December, 2012

## ACT No. XXI of 2012

*AN ACT to provide for the protection of human embryos and other ancillary matters.*

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same as follows:-

Short title and commencement.

**1.** (1) The short title of this Act is the Embryo Protection Act, 2012.

(2) This Act shall come into force on such date as the Minister responsible for justice, with the concurrence of the Minister responsible for health, may by notice in the Gazette establish, and different dates may be so established for different provisions and different purposes thereof.

Interpretation.

**2.** In this Act, unless the context otherwise requires:-

"Authority" means the Embryo Protection Authority established by article 3;

Cap. 464.

"the Council" means the Medical Council established by article 9 of the Health Care Professions Act;

"Directive" means the Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 on setting

standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

"embryo" means the human organism that results from the fertilisation of a human egg cell by a human sperm cell which is capable of developing and shall further include each totipotent cell removed from a human embryo or otherwise produced, that is assumed to be able to divide and to develop as a human being under the appropriate conditions;

"germ line cells" means all egg and sperm cells which may lead to the resultant human being;

"health care professional" shall have the same meaning assigned to it by article 2 of the Health Care Professions Act; Cap. 464.

"medically assisted procreation" means that process whereby an embryo would develop following the bringing together of gametes, which process would have been aided or assisted by means which go beyond the workings of the natural process, and which includes all types of intervention, be they intracorporeal or extracorporeal that help the bringing together of gametes, and their implanting or the implanting of the embryo that could have developed from this intervention within the reproductive system of the female;

"medical practitioner" means a person licensed under the Health Care Professions Act to practice as a medical practitioner; Cap. 464.

"Minister" means the Minister responsible for health;

"prospective parent" means either of two persons of the opposite sex who are united in marriage, or who have attained the age of majority and are in a stable relationship with each other.

Establishment and composition of the Embryo Protection Authority.

**3.** (1) There shall be a body, to be known as the Embryo Protection Authority, which shall consist of a Chairman and such number of other members not being less than four who shall be appointed by the Minister.

(2) The Chairman shall be a person in possession of a warrant to exercise the profession of Advocate and who has exercised that profession for at least twelve years or a retired Judge or a retired Magistrate.

(3) A person shall not be qualified to hold office as a member of the Authority if he:

(a) is a Minister or Parliamentary Secretary;

(b) is a member of, or a candidate for election to, the House; or

(c) is a member of a local government authority; or

(d) has a financial or other interest in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Authority.

(4) Subject to the provisions of this article, the office of a member of the Authority shall become vacant -

(a) at the expiration of five years from the date of his appointment or at such earlier time as may be specified in the instrument by which he was appointed; or

(b) if any circumstances arise that, if he were not a member of the Authority, would cause him to be disqualified for appointment as such.

(5) A member of the Authority may be removed from office by the Minister if, in the opinion of the Minister, such member is unfit to continue in office or has become incapable of properly performing his duties as a member, whether arising from infirmity of mind or body or any other cause, or for misbehaviour.

(6) If the office of a member of the Authority is vacant or if a member is for any reason unable to perform the functions of his office, the Minister may appoint another person as a temporary member of the Authority until the member who was unable to perform the functions of his office resumes those functions.

(7) The members of the Authority, in the exercise of their functions, shall act on their own individual judgement and shall not be subject to the direction or control of any person or authority.

Functions and powers of the Authority.

**4.** (1) The functions and powers of the Authority shall be the following:

(a) to ensure that high standards of ethics are maintained by all medical practitioners, paramedics and other personnel involved in procedures of medically assisted procreation;

(b) to request and obtain, in cases of reasonable suspicion that the provisions of this Act are not being followed,

information and copies, in any form, of documents required by the Directive to ensure traceability of human cells;

(c) to carry out inspections in order to ensure that the standards of best practice are being respected and implemented and that all information and documentation required under article 18 is being kept appropriately and for this purpose to access clinics and any other places as necessary;

(d) to maintain a statement of the general principles which, in its opinion, should be followed:

(i) in carrying out its activities under this Act; and

(ii) in carrying out its functions in relation to such activities under this Act;

(e) to ensure, in relation to activities under this Act, compliance with:

(i) the obligations and requirements imposed by or under this Act; and

(ii) the codes of practice established under paragraph (a);

(f) to perform such other functions as may, from time to time, be prescribed by regulations made under this Act.

(2) Notwithstanding the provisions of article 7 but subject to the provisions of article 18, the Authority may give for adoption the fertilized egg cells, in the case where, after the fertilization of the egg cells but before the implantation of the fertilized embryos into the womb has taken place, death of the woman ensues or where for any other reason the implantation of the fertilized embryo into the womb cannot take place.

(3) Nothing in this article shall prejudice the authority or the exercise of any function or power of the Licencing Authority under the Human Blood and Transplants Act: Cap. 483.

Provided that during the period from the day in which the implantation of the fertilized embryo into the womb cannot take place for the reasons mentioned in this article until the day of giving the embryo for adoption, the Authority shall be deemed to be curator of the embryo for all intents and purposes of the law and the Authority shall immediately and during the duration of the curatorship inform

and consult with the prospective parent or parents, or in their absence their legal heir, on the decisions which need to be taken on the embryo. In the case that both prospective parents can still be consulted, the Authority shall, in so far as it is possible, respect the wishes of the prospective parents within the parameters of this Act:

Provided that any prospective parent or parents, or in their absence their legal heir, within twenty days from the date of decision of the Authority for giving for adoption the fertilized egg cells or within one year from the day in which the implantation of the fertilized embryo into the womb could not take place for a reason or reasons above mentioned, file an application taken upon oath asking the Civil Court (Family Section) to decide in the supreme interest of the embryo to whom the embryo should be given for adoption.

Entitlement to medically assisted procreation procedures.

**5.** (1) Any prospective parent shall have access to medically assisted procreation procedures:

Provided that these procedures may only be resorted to where there is a reasonable chance of success and the procedures do not entail any known undue risk to the health of the woman or the child, beyond those already well known as inherently associated with the procedure itself.

(2) Any person who provides, or assists in, any medically assisted procreation procedure to a person other than a prospective parent shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner, who performs the said procedure, the medical practitioner shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person on whom the procedure was performed or attempted was entitled to access to such procedure.

Unlawful procedures.

**6.** Whosoever –

(a) artificially fertilizes any egg cell for any purpose other than that of bringing about the pregnancy of the woman from whom the cell originated;

(b) intentionally fertilizes more than two egg cells from one woman within one treatment cycle:

Provided that in exceptional cases the medical practitioner in charge of the medically assisted procreation may

decide to transfer up to a maximum of three fertilized egg cells from one woman within one treatment cycle provided that this is done in accordance with a protocol established in writing by the Authority after consulting the associations which, according to law, represent the medical practitioners who exercise their profession in the fields of obstetrics and paediatrics. Such a protocol shall include, without prejudice to other criteria, clear criteria regarding the age of the woman who will be participating in such a procedure and after how many cycles in accordance with paragraph (b) may the medical practitioner decide to fertilize up to a maximum of three egg cells:

Provided further that the above mentioned Protocol may be substituted by a Protocol agreed upon by the Authority and the associations which, according to law, represent the medical practitioners who exercise their profession in the fields of obstetrics and paediatrics which specifies in a detailed manner the best medical practice in the field of medically assisted procreation. If such an agreement on a Protocol between the Authority and the associations cannot be agreed upon, then the Protocol established in writing by the Authority under the first proviso shall apply:

Provided further that authenticated copies shall be sent within two days to the Minister responsible for Health and the Speaker of the House of Representatives. The Speaker of the House of Representatives, or in his absence the Deputy Speaker, shall put the authorised copy of the document on the Table of the House on the next first Parliamentary sitting:

Provided further that where the person is a medical practitioner, no criminal proceedings can be undertaken against that medical practitioner if the medical practitioner is strictly acting in good faith and according to the Protocol mentioned;

(c) does not transfer all embryos produced into a woman within one treatment cycle;

(d) removes an embryo from a woman before the completion of implantation in the womb in order to transfer the embryo to another woman;

(e) selects or discards an embryo for eugenic purposes;

(f) carries out an artificial fertilization of, or transfers a human embryo into, a woman who is prepared to give up her child permanently after birth (surrogate mother),

shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that -

(i) the woman from whom the egg cell or embryo originated, in respect of the conduct referred to in paragraphs (a) and (d); and, or

(ii) the woman into whom the egg cell or embryo will be transferred, in respect of the conduct referred to in paragraph (f);

shall have the punishment decreased by one or two degrees.

Prohibition of preservation of embryos.

**7.** All forms of preservation, including cryo-preservation of embryos are prohibited and whosoever contravenes this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that where the transfer of the fertilized embryos into the womb is not possible owing to grave and certified *force majeure* not predictable at the moment of fertilization, it shall be lawful to preserve such embryos up to the date of such transfer which shall take place as soon as possible:

Provided further that when there has been a breach of any provision of this Act, the Authority may order the freezing of any embryo to preserve its life.

Improper use of human embryos.

**8.** (1) Whosoever, other than for the purpose of implantation in a woman as may be authorized by the provisions of this Act disposes of, hands over or acquires a human embryo produced outside the body, or removes such embryo from a woman before the completion of implantation in the womb, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

(2) Whosoever causes a human embryo to develop further outside the body for any purpose other than in order to bring about a

pregnancy, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

Improper use etc., of gametes.

**9.** The use, transfer or the fertilisation of any germ line cells not originating from the prospective parent is prohibited and any person, who contravenes this article shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner he shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person from whom the germ line cells originated was a prospective parent within the meaning of this Act.

Prohibition of selection of sex.

**10.** (1) Whosoever artificially fertilizes a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be guilty of an offence and, on conviction, shall and liable to the punishment of a fine (*multa*) of not less than four thousand euro (€4,000) and not exceeding ten thousand euro (€10,000).

(2) Nothing contained in sub-article (1) shall be understood as preventing the selection of a sperm cell by a medical practitioner in order to prevent the child from falling ill with a sex-linked genetic illness.

Prohibition of cloning.

**11.** (1) Any intervention seeking to create a human being genetically identical to another embryo, *foetus*, or human being, whether living or dead, is prohibited and for the purpose of this article, the term "genetically identical" means a human being sharing with another the same nuclear gene set.

(2) Whosoever intervenes or participates in any artificial intervention as referred to in sub-article (1) shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

(3) Whosoever transfers into a woman an embryo as referred to in sub-article (1) shall be liable to the same punishment laid down in sub-article (2).

Unauthorised fertilisation, embryo transfer, and artificial fertilisation after death.

**12.** (1) Whosoever -

(a) artificially fertilizes an egg cell without the consent of the woman, whose egg cell is to be fertilized, or without the consent of the man, whose sperm cell will be used for fertilization;

(b) transfers an embryo into a woman without her consent;

(c) knowingly artificially fertilizes an egg cell with the sperm of a man after his death,

(d) knowingly artificially fertilizes an egg cell of a woman after her death,

shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-five thousand euro (€25,000):

Provided that the punishment shall be decreased by one or two degrees -

(i) as regards the woman whose egg has been fertilized, in respect of paragraph (c); and

(ii) as regards the man whose sperm was used for fertilisation in respect of paragraph (d).

(2) Nothing in this Act shall be construed or interpreted in a way as to impede, for medical reasons and according to accepted medical norms, the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage by the same person from whom the sperm or egg was taken and frozen for the generation of an embryo with a person of the opposite sex:

Provided that nothing in this Act shall be construed as allowing, at any stage, the transfer and, or donation of the human egg cells and, or the human sperm cells.

Prohibition of artificial alteration of human germ line cells.

**13.** (1) Subject to the provisions of sub-article (3), whosoever shall willfully alter in an artificial way the genetic information of a human germ line cell shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

(2) Whosoever knowingly uses a human germ line cell with artificially altered genetic information for fertilization shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) No offence shall arise, against the medical practitioner carrying out the medically assisted procedure, under sub-article (1) where the alteration of the genetic information of a germ line cell is the unintended consequence of inoculation, radiation or chemotherapeutic or treatment.

Prohibition of formation of chimerae and hybrids.

**14.** (1) Whosoever-

(a) unites embryos with different genetic material to a cell conglomerate using at least one human embryo; or

(b) joins a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further; or

(c) fertilizes a human egg cell with the sperm of an animal or fertilizes an animal's egg cell with the sperm of a man, with the intention of generating an embryo capable of development,

shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) not less than ten thousand euro (€10,000) and not exceeding seventy thousand euro (€70,000) or to imprisonment not exceeding seven years or to both such fine and imprisonment.

(2) Whosoever transfers to a woman or an animal an embryo arising out of a procedure described in sub-article (1) or transfers to an animal a human embryo shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

Prohibition of experimentation on human embryos.

**15.** (1) Any experimentation on human embryos is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) not exceeding seventy thousand euro (€70,000) and to imprisonment not exceeding seven years.

(2) The creation of human embryos for the purpose of research or experimentation or for any other purpose not permitted under this Act is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) Clinical interventions on a human embryo are allowed on condition that said interventions pursue an exclusively diagnostic and, or therapeutic purpose related to the embryo and are in the interests of the health and development of the embryo itself:

Provided that no other alternative medical method or procedure is available and the consent of the prospective parents has been given in writing and there is no undue risk to the embryo and to the mother.

Wilful cause of death of embryos.

**16.** (1) Whosoever wilfully causes the death of any embryo shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) not exceeding twelve thousand euro (€12,000) or to imprisonment not exceeding two years or to both such fine and imprisonment.

(2) This article shall also apply to any human clone created in breach of article 11.

Application of articles 121D and 248E(3) of the Criminal Code. Cap. 9

**17.** The provisions of articles 121D and 248E(4) of the Criminal Code shall, *mutatis mutandis*, apply to persons found guilty of an offence under this Act.

Informed consent.

**18.** (1) The consent of both prospective parents who are to have access to medically assisted procreation procedures is to be expressed jointly in writing in such form, as may be prescribed by regulations under this Act, to, and in the presence of the medical practitioner in charge of the procedure:

Provided that such consent may only be withdrawn in writing by either of the prospective parent before fertilisation.

(2) For the purposes of informed consent and before applying any procedure leading to medically assisted procreation, the medical practitioner in charge of the procedure shall inform in detail and in writing both prospective parents on:

(a) the methods and treatment of any procedure to be employed;

(b) the complications that may arise for the woman and potential offspring;

(c) the probable chances of success of the said procedure;

(d) all the risks involved to both prospective parents and the offspring;

(e) the possible psychological effects as a result of the application of the said procedure to both prospective parents and offspring;

(f) the bioethical issues, including the freezing process involved as referred to in article 4(2); and

(g) where applicable, on the cost of the entire procedure.

(3) The medical practitioner in charge of the procedure shall ensure that the prospective parents respectively receive independent clinical counselling before, throughout and after the procedure.

(4) Every medical practitioner responsible for a procedure of medically assisted procreation shall ensure that a copy is kept of all the documentation required under this Act, including such documentation certifying that the informed consent required under this article was obtained after the same medical practitioner gave the prospective parents all the information and after ensuring that both prospective parents received the required counselling.

Status of child born.

**19.** Any child born as a result of any medically assisted procreation procedure shall be considered to be the child of the prospective parents who have expressed their consent in writing as provided in article 18 and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parents without the intervention of any procedure as aforesaid; and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status as the direct descendant of such prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

Conscientious objection.

**20.** (1) A health care professional is under no obligation to participate in any procedure for the application of any technique of medically assisted procreation regulated by this Act when such professional considers such participation objectionable as a matter of conscience and declares his objection beforehand. Such a declaration shall be communicated within three months from the coming into force of this Act, to the Authority and to the director of the hospital or medical establishment with whom the health care professional is employed.

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(2) The objection declared as provided in sub-article (1) may be revoked or the said objection may be declared even after the lapse of the period referred to in sub-article (1) but in such a case the declaration raising the objection shall only come into effect after the lapse of a month from the date of its communication as provided in sub-article (1).

(3) The objection declared as provided in sub-articles (1) or (2) shall have the effect of exempting the health care professional who makes the declaration from any participation in any procedure or activity specifically and necessarily directed towards the implementation of the technique or procedure leading to a medically assisted procreation but does not exempt him from providing assistance before or after the said procedure or activity.

Additional penalties.

**21.** Without prejudice to any punishment as may be prescribed by this Act or by any other law, where the person convicted of an offence under this Act is a medical practitioner or a health care professional, the Court shall order that a copy of the judgment be served upon the competent council under the Health Care Professions Act and on the Minister.

Cap. 464.

Licence for premises.

**22.** No premises may be used for any activity related to medically assisted procreation unless the premises are licensed for the purpose by the Licensing Authority according to the Human Blood and Transplants Act and any regulations made thereunder.

Power to make regulations.

**23.** The Minister shall, with the concurrence of the Minister responsible for justice, have power to make regulations to:

(a) prescribe anything which may be prescribed for the implementation and execution of the provisions of this Act;

(b) regulate the licensing of any premises used for the execution of any procedure of medically assisted procreation including the conditions required for a medical practitioner to practice any such procedure in such premises;

(c) lay down any conditions for the execution of such procedures of medically assisted procreation.

Passed by the House of Representatives at Sitting No. 528 of the 26th November, 2012.

MICHAEL FRENDO

*Speaker*

RAYMOND SCICLUNA
*Clerk to the House of Representatives*