

### Abbozz ta' liġi imsejjah

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

IL-PRESIDENT, bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqa' f'dan il-Parlament, u bl-awtorità tal-istess, hareġ 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-sehħ.

(2) Dan l-Att għandu jidhol fis-sehħ fil-jum li l-Ministru responsabbli għall-ġustizzja flimkien mal-Ministru responsabbli għas-saħħa, jistabilixxi b'avviż fil-Gazzetta, u dati differenti jistgħu jġu stabbiliti għal skopijiet u disposizzjonijiet differenti ta' dan l-Att.

2. F'dan l-Att sakemm ir-rabta tal-kliem ma tehtiegħ 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 jinholq bniedem;

"embrijun" tfisser il-fertilizzazzjoni ta' ċellola tal-bajd umana minn ċellola tal-isperma umana li tkun kapaċi tiżviluppa u għandha wkoll tinkludi kull ċellola totipotenti imneħhija minn embrijun jew prodott mod ieħor, li hija prezunta li tista' tiddividi ruħha u tiżviluppa

C 480

bhala bniedem uman taht il-kundizzjonijiet xierqa;

"ġenitur prospettiv" tfisser wiehed jew wahda minn żewġ persuni tas-sess oppost li huma marbutin bir-rabta taż-żwieġ, jew li jkunu laħqu l-età magġuri u li huma f'relazżjoni stabbli ma' xulxin.

Kap. 464.

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

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

Kap. 464.

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

Kap. 464.

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

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

**3.** (1) Għandu jkun hemm korp, li jkun magħruf bhala 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) 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

(c) 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-twetiq tal-funzjonijiet tagħha bhala membru tal-Awtorità.

(3) Bla ħsara għad-disposizzjonijiet 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 cirkostanza li, kieku persuna ma kienetx membru tal-Awtorità, kienet iġġib l-iskwalifika tagħha għal dik il-ħatra.

(4) 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 minhabba f'nuqqas ta' saħħa tal-mohħ jew tal-ġisem jew għal xi raġuni oħra, jew minhabba f'imġieba hazina.

(5) 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' jahtar persuna oħra bħala membru temporanju tal-Awtorità sakemm il-membri li ma setgħax iwettaq il-funzjonijiet tal-kariga tiegħu jerga jidhol f'dik il-kariga.

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

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

Funzjonijiet u setgħat tal-Awtorità.

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

(b) li toħroġ liċenzi lill-kliniki li japplikaw għal reġistrazzjoni u sabiex twettaq spezzjonijiet b'mod regolari sabiex tiżgura li l-istandards tal-aħjar Prattika qed jiġu rispettati u implimentati;

(c) li toħroġ ċertifikati rigward l-eligibilità tal-ġenituri prospettivi għal trattamenti li għandhom x'jaqsmu ma' prokreazzjoni assistita b'mod mediku;

(d) li żzomm taħt monitoraġġ informazzjoni dwar embrijuni u kull żvilupp sussegwenti ta' embrijuni u dwar l-ġhoti ta' servizzi ta' kura jew attivitajiet regolati b'dan l-Att, u sabiex tagħti parir lill-Ministru, jekk hekk jitlob, dwar dawn il-materji;

(e) li ttiprovdi, sa dak il-limitu li tikkonsidra xieraq, parir u informazzjoni lil persuni li għalihom tapplika l-liċenza jew lill-ġenituri prospettivi li jkun qad jirċievu trattament għall-finijiet ta' attivitajiet regolati b'dan l-Att, jew lil kull min jixtieq jagħmel hekk;

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

C 482

(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;

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

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

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

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

(2) Minkejja d-disposizzjonijiet tal-artikolu 7, iżda mingħajr ħsara għad-disposizzjonijiet tal-artikolu 18, l-Awtorità tista' tagħti għal adożzjoni 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.

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:

Izda 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.

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

Izda meta l-persuna tkun tabib li jkun wettaq l-imsemmija proċedura, it-tabib għandu jiġi eżentat mir-responsabbiltà 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 b'hal dik.

Proċeduri illegali.

**6.** Kull min –

(a) jiffertilizza b'mod artifiċjali xi ċellola tal-bajd għal

kull skop hlied dak sabiex tiġi t-tqala tal-mara minn fejn originat iċ-ċellula;

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

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

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

(e) jagħzel 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 jitwield jew titwield (omm surrogata),

tkun haġta ta' reat u tehel multa ta' mhux anqas minn hamest elef euro (€5,000) u mhux aktar minn hmistax-il elf euro (€15,000) jew prigunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-prigunerija flimkien:

Izda -

(i) il-mara li minnha jkunu originaw 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 iċ-ċellola tal-bajd jew l-embrijun, fir-rigward tal-aġir imsemmi fil-paragrafu (f);

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

7. Kull forma ta' preservazzjoni, inkluż il-krijo-preservazzjoni ta' embrijuni, hija projbita u kull min jikser xi disposizzjoni ta' dan l-artikolu ikun haġi ta' reat u jehel meta jinsab haġi multa ta' mhux anqas minn hamest elef euro (€5,000) u mhux aktar minn hmistax-il elf euro (€15,000) jew prigunerija ta' mhux aktar minn tliet snin jew dik il-multa u l-prigunerija flimkien:

Projbizzjoni ta' preservazzjoni ta' embrijuni.

Izda meta t-trasferiment fil-guf tal-embrijun fertilizzat ma jkunx possibbli minhabba forza maġġuri gravi u ppruvata li ma tkunx giet preveduta fil-mument tal-fertilizzazzjoni, dawn l-embrijuni jistgħu jiġu preservati sad-data ta' dak it-trasferiment liema

trasferiment għandu jsir mill-aktar fis possibbli:

Iżda wkoll meta jsir xi ksur ta' xi disposizzjoni 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-finjiet ta' implantazzjoni f'mara kif hekk awtorizzat bid-disposizzjonijiet 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 hati ta' reat u jeħel meta jinsab hati 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 finjiet barra minn dawk sabiex tiġi t-tqala, ikun hati ta' reat u jeħel meta jinsab hati 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 disposizzjoni ta' dan l-artikolu tkun hati 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-responsabbiltà 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 hati 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 tintfiehemi li tipprevjeni s-selezzjoni ta' ċellola tal-isperma minn tabib sabiex jiġi preservat 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 jinholq bniadem ġenetikament identiku ma' embrijun ieħor, *foetus*, jew bniadem,

kemm ħaj jew mejjet, huwa projbit u għal finijiet ta' dan l-artikolu l-kliem "ġenetikament identiku" jfissru bniedem li jaqsam ma' iehor l-istess sett ta' ġene nukleari.

(2) Kull min jintervjeni jew jipparteċipa f'xi intervent artifiċjali kif imsemmi fis-subartikolu (1) jkun hati ta' reat u jehel 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) jehel l-istess piena stabbilita fis-subartikolu (2).

## 12. 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;

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

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

Izda l-piena tiġi mnaqqsa b'grad wiehed jew żewġ gradi -

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

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

13. (1) Mingħajr ħsara għad-disposizzjonijiet tas-subartikolu (3), kull min xjentement jibdel b'mod artifiċjali l-informazzjoni ġenetika ta' ċellola *germ line* umana, ikun hati ta' reat u jehel 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-

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

C 486

prigunerija 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 jikkaguna 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 prigunerija ta' mhux aktar minn seba' snin jew dik il-multa u l-prigunerija 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-disposizzjonijiet 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 prigunerija ta' mhux aktar minn seba' snin jew dik il-multa u l-prigunerija flimkien.

(2) Il-holqien ta' embrijuni umani, għall-finijiet ta' rikerka u esperimenti jew għal xi għan iehor mhux permess taħt dan l-Att, huwa pprojbit u kull min jikser id-disposizzjonijiet 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:

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

**16.** (1) Kull min jiddistruggi b'mod volontarju xi embrijun ikun ħati ta' reat u jeħel meta jinsab ħati multa ta' mhux aktar minn tna-x-il elf euro (€12,000) jew prigunerija ta' mhux aktar minn sentejn jew dik il-multa u l-prigunerija flimkien.

Id-distruzzjoni b'mod volontarju ta' embrijuni.

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

17. Id-disposizzjonijiet tal-artikoli 121D u 248E(4) tal-Kodiċi Kriminali għandhom *mutatis mutandis* japplikaw għal persuna li tkun instabet haġja 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 kongunt 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.

Izda dan il-kunsens jista' jiġi irtirat biss bil-miktub minn wiehed 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;

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

C 488

(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 pariri xierqa approvati mill-Awtorità qabel ma ssir il-proċedura.

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 civili 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.

Ogġezzjoni tal-kuxjenza.

**20.** (1) Professjonist fil-kura medika ma huwa taħt l-ebda obbligu biex jipparteċipa 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-partiċipazzjoni ogġezzjonabbli bħala kwistjoni ta' kuxjenza u jiddikjara din l-ogġezzjoni min qabel. Din id-dikjarazzjoni għandha tintbagħat, fi żmien tliet xhur mid-data ta' meta dan l-Att jiġi fis-seħħ, lid-direttur tal-isptar jew l-istabiliment mediku fejn jaħdem il-professjonist fil-kura medika.

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

(3) Din l-ogġezzjoni 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 intiza għall-implimentazzjoni tat-teknika jew proċedura li twassal għall-prokreazzjoni assistita b'mod mediku iżda ma tezentahx milli jipprovdi għajjnuna 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 haġta 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.** (1) L-ebda post ma jista' jintuża għal xi attività li għandha x'taqsam ma' prokreazzjoni assistita b'mod mediku sakemm dan il-post ikun speċifikament liċenzjat skont id-disposizzjonijiet ta' dan l-Att.

Liċenza għal  
post.

(2) Meta tingħata din il-liċenza l-Awtorità tista' żżid dawk il-kondizzjonijiet mal-liċenza kif jidhrilha xieraq, u b'mod partikolari, iżda bla ħsara għas-setgħa ġenerali tagħha, dawk il-kondizzjonijiet li għandhom x'jaqsmu, skont kull każ, mal-post li jkun qed jintuża għal dawn il-proċeduri ta' prokreazzjoni assistita b'mod mediku, *inter alia*, dawk li għandhom x'jaqsmu ma' tagħmir, apparat, struttura, spazju u akkommodazzjoni.

(3) Kull min iwettaq reat taħt dan l-artikolu jkun haġi ta' reat u jehel meta jinsab haġi multa ta' mhux aktar minn tnax-il elf euro (€12,000) jew priġunerija ta' mhux aktar minn sena jew dik il-multu u l-priġunerija flimkien.

**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-disposizzjonijiet 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;

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

### Għanijiet u Raġunijiet

C 490

L-għanijiet ta' dan l-Abbozz huma sabiex jiġu regolati proċeduri rigward il-prokreazzjoni assistita b'mod mediku u sabiex jiġu protetti l-embrijuni umani.

---

**A Bill  
entitled**

*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:-

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

(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.

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

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

"the Council" means the Medical Council established by article 9 of the Health Care Professions Act; Cap. 464.

"embryo" means 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 an 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 Cap. 464.

C 492

to it by article 2 of the Health Care Professions Act;

Cap. 464.

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

"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) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

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

(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 issue licences to clinics that apply for registration and to carry out regular inspections in order to ensure that the standards of best practice are being respected and implemented;

(c) to issue certificates regarding eligibility of the prospective parents for treatments relating to medically assisted procreation;

(d) to keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities regulated by this Act, and advise the Minister, if he so requests, about those matters;

(e) to provide, to such extent as it considers appropriate, advice and information to persons to whom licences apply or prospective parents receiving treatment for the purpose of activities regulated by this Act, or who may wish to do so;

(f) 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;

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

C 494

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

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

(h) 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.

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.

(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;

(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.

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:

Prohibition of preservation of embryos.

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.

C 496

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 be 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 be 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 preserve 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 be 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).

**12.** 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).

**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 be 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.

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

Prohibition of artificial alteration of human germ line cells.

C 498

(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 be 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 be 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.

**16.** (1) Whosoever willfully destroys 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.

Wilful  
destruction of  
embryos.

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

**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.

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

**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:

Informed  
consent.

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;

C 500

(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 receive proper counselling as approved by the Authority prior to the procedure.

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 director of the hospital or medical establishment with whom the health care professional is employed.

(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.

**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.

Additional penalties.

Cap. 464.

**22.** (1) Premises may not be used for any activity relating to medically assisted procreation unless they are specifically licensed by the Authority according to the provisions of this Act.

Licence for premises.

(2) In granting such licence the Authority may attach such conditions to the licence as it deems fit and in particular, but without prejudice to its general power, such conditions as relate, according to each case, to the premises used for such medically assisted procreation, such conditions which, *inter alia*, relate to hygiene, equipment, implements, structure, space and accommodation.

(3) Whosoever commits an offence under this article and, on conviction, shall liable on conviction to a fine (*multa*) not exceeding twelve thousand euro or to imprisonment not exceeding one year or to both such fine and imprisonment.

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

Power to make regulations.

(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.

---

### **Objects and Reasons**

The objects of this Bill are to regulate the procedure relating to medically assisted procreation and to protect human embryos.