Independent Placenta Encapsulation Network Ltd

Code of Practice for Licensed IPEN Placenta Encapsulation Specialists

ARTICLE 1: CLIENT CARE

SECTION 1.01 - Confidentiality
IPEN Specialists are committed to maintaining the highest degree of integrity in all our dealings with potential, current and past clients, both in terms of normal commercial confidentiality, and the protection of all personal information received in the course of providing the business services concerned. Personal information obtained from our clients is confidential and will not be shared with third parties however some of the information (i.e. number of capsules made) may be used for statistical information where names are not given. The Client must be offered the opportunity to opt out of the collection of this data.

SECTION 1.02 - Duty of care
IPEN Specialist actions and advice should always conform to relevant law and reflect the regulations given by the appropriate governing bodies and local authorities as we believe that all businesses and organizations, including our Network, should avoid causing any adverse effect on the human rights of people in the organisations we deal with, the local and wider environments, and the well-being of society at large. Specialists take care in understanding the sensitivity of the service provided, being invited into the lives of their Clients at such a unique moment, often visiting our Clients in their hospital ward or own homes. We always ensure we carry out our services to the highest standard to reduce or eliminate any risks to either the Client or the Specialists themselves.

SECTION 1.03 - Fees
Specialist fees are to remain affordable for the service provided, which is high quality, specialised service. As such Specialists are advised (but not obliged) to charge between £125-250 per encapsulation. Specialists must agree fees and basis of charges clearly in advance with all Clients so that Specialists and Clients can plan reliably for what lies ahead and how the service is to be delivered.

SECTION 1.05 - Payment
Specialists aim to be flexible with their Clients in the way that the services are charged. Specialists should attempt to arrange payment for services before or on the date of the service provided to avoid conflict.

SECTION 1.06 - Quality assurance
Specialists maintain the quality of service through constant ongoing review from IPEN. IPEN encourages regular contact with Specialists and requires Specialists to submit Client Report forms monthly to maintain high standards of service and reducing or eliminating risks.

SECTION 1.07 - Professional conduct
Specialists must conduct all activities professionally and with integrity taking great care to be completely objective in relation to judgements and any recommendations that are given so that issues are never influenced by anything other than the best and proper interests of the Client. Specialists vary in experience and should only give advice where appropriate qualifications and training allows for the advice or information to be given.

SECTION 1.09 - Equality and discrimination
Specialists strive to be fair and objective when giving advice and we are never influenced in our decisions, actions or recommendations by issues of gender, race, creed, colour, age or personal disability.

SECTION 1.10 – Working within a Network
Specialists are a part of the IPEN Network and represent the Network as a whole through the service they provide in their local area. IPEN Specialists must act professionally and follow the IPEN Code of Practice when representing IPEN at functions and events or when serving clients. Although working independently around the world, IPEN Specialists must always ensure the services they provide meet IPEN's high standards at all

times. Specialists often work closely with one another and must always conduct themselves respectfully and with integrity when providing services to clients or working with other IPEN Specialists. As part of a team, Specialists are given the opportunity to share ideas, contribute to improving IPEN and attend annual meetings.

ARTICLE 2: HEALTH AND SAFETY

Training: IPEN Placenta Specialists are trained to follow strict guidelines for Services approved by UK agencies, The Health Protection Unit and Decorum Environmental Health Office. The Specialist must also keep up to date Certificates in both Food Hygiene for Manufacturing and Infection Control. Placenta Encapsulation as a process requires careful planning to ensure the safety of both the Specialist and the Client. A placenta Specialist's duty is to prepare the placenta from each client into the desired product of consumable placenta capsules or other placenta remedies as taught by IPEN. This process will take place in either the client's home or the Specialist's home. When handling the placenta it is important to ensure hygiene and sterilisation is of utmost importance to reduce and/or eliminate the risk of contamination. Specialists are to adhere to current government regulations when providing placenta services.

SECTION 2.01 – Current Government Regulations

Health and Safety at Work etc Act 1974 requires:
Management of Health and Safety at Work Regulations (MHSWR)1999 require employers and self-employed workers to:

- employers and self-employed workers to ensure they provide and maintain workplaces, equipment and systems of work that are, so far as is reasonably practicable, safe to workers and the public;
- eployees to take care of their own and others' health and safety, and to co-operate with their employer or any other person to enable them to comply with health and safety duties;
- *A guide to the Health and Safety at Work etc Act 1974 (L1)* gives further information.
- identify the measures they need to take by carrying out risk assessments;
- institute safety management systems;
- appoint persons to assist in health and safety management;
- ensure co-ordination and co-operation where two or more employers or self-employer persons share a workplace;
- make emergency arrangements;
- provide information and relevant training for employees;
- *Successful health and safety management (HSG 65)* gives further information.

Control of Substances Hazardous to Health (COSHH) Regulations 2002 provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents.
These actions include:
Genetically Modified Organisms (Contained Use) Regulations 2000
and Genetically Modified Organisms (Contained Use) (Amendment)
Regulations 2002 require employers and self-employed workers to:

- assess the risk;
- prevent the risk by substitution if possible;
- control the risks using appropriate measures *e.g. work process, systems and engineering controls;*
- control exposure at source *e.g. adequate ventilation systems and appropriate organisational measures;*
- control the working environment including general ventilation;
- maintain, examine and test control measures;
- provide suitable personal protective equipment (PPE) when adequate control of exposure cannot be achieved by other means;
- monitor exposure at the workplace;
- provide information, instruction and training for workers;
- make arrangements for health surveillance of workers where necessary;
- *COSHH: a brief guide to the regulations (INDG131 rev1);*

Control of Substances Hazardous to Health (Fourth edition). The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance (L5);

- make a risk assessment for genetically modified microorganisms in relation to human health and environmental protection and for genetically modified animals in relation to human health;
- apply appropriate containment and control;
- notify the Competent Authority to the Regulations of all premises being used for genetic modification;
- notify the Competent Authority of certain activities;
- *A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000*, and *Contained use of genetically modified organisms (INDG86 rev2)* give further information.

Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection.
2 published: 2 June 2003
Health Surveillance under COSHH: guidance for employers; *The management, design and operation of microbiological containment laboratories*; and *5 steps to risk assessment (INDG163 rev1)* give further information.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 require employers and the self-employed to:
The Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations 1996 require consigners to:

- report any infection reliably attributable to work with live or dead humans or animals, exposure to blood or fluids or any potentially infected material derived from any of the above;
- report any accident or incident that could result in the release of a TSE agent (or any other biological agent categorised in Hazard Group 3 or 4). *e.g.* percutaneous exposure to known infected brain material;
- *Guide to the reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995* gives further information.

SECTION 2.02 – Introduction to Risks

The most serious factor to consider when working with human tissue is the types of pathogens that may be present in the blood and tissue, taking into account the distribution of specific pathogens within the body, and the likelihood that they will be present given the source.

When working with blood tissue Specialists must assume all clients carry disease even though these questions have been asked upon booking the service. Specialists are most at risk of diseases HIV/AIDS, Hepititus B, Hepititus C and CJDs. All Specialists will be made aware of these diseases and their severity, including the risks involved when handling the placenta during their training as a placenta specialist. Specialists are instructed to review the IPEN Risk Assessment for an in depth review of the individual risks involved with the Services.

SECTION 2.03 – Details of Bloodborne Diseases Presenting Possible Risks

(a.) HIV/AIDS: HIV is a sexually transmitted virus and AIDS is the progressive immune failure that HIV causes. HIV/AIDS is a syndrome resulting from the acquired deficiency of cellular immunity caused by the human immunodeficiency virus (HIV). It is characterized by the reduction of the Helper T-lymphocytes in the peripheral blood and the lymph nodes; opportunistic infections (usually pneumocystis carinii pneumonia, cytomegalovirus (CMV) infections, tuberculosis, candida infections, and cryptococcosis); and the development of malignant neoplasms (usually non-Hodgkin's lymphoma and Kaposi's sarcoma). The human immunodeficiency virus is transmitted through sexual contact, sharing of contaminated needles, or transfusion of contaminated blood. Generalized lymphadenopathy, fever, weight loss, and chronic diarrhea are common symptoms of AIDS. The patients usually die either of opportunistic infections or malignant neoplasms.
Source - Diseases Database http://www.diseasesdatabase.com/

(b.) Hepatitis B: Hepatitis means inflammation of the liver and can have many causes, the most common of which is an infection with a hepatitis virus. Hepatitis B is relatively uncommon in the UK. High-risk

areas for hepatitis B include South-East Asia, Africa, the Middle East, the Far East and southern and eastern Europe. Hepatitis B is highly contagious, which means it can be passed from person to person very easily. It's 50 to 100 times more contagious than HIV (human immunodeficiency virus). The virus is present in body fluids such as blood, saliva, semen and vaginal fluid. Hepatitis B can be acute or chronic. An acute illness is typically over quite quickly. The term acute refers to the length of time a person has had it, not how serious a condition is. Chronic hepatitis B lasts for more than six months, sometimes for the rest of a person's life. The term chronic refers to time, not how serious a condition is. Babies and young children who become infected with hepatitis B have a very high chance of becoming carriers, which means they are infectious. Only between two and 10 adults out of 100 infected with hepatitis B will develop a chronic infection. Source: Bupahttp://hcd2.bupa.co.uk/fact_sheets/html/hepatitis_b.html

(c.) Hepatitis C: Hepatitis C is a blood-borne virus that predominantly infects the cells of the liver. This can cause inflammation of and sometimes significant damage to the liver and affect its ability to perform its many, varied and essential functions. Although it has always been regarded as a liver disease (hepatitis means inflammation of the liver), recent research has shown that hepatitis C affects a number of other areas of the body including the digestive system, the lymphatic system, the immune system and the brain. Hepatitis C was discovered in the 1980s when it became apparent that there was a new virus (not hepatitis A or B) causing liver damage. It was known as non-A non-B hepatitis until it was properly identified in 1989. A screening process was developed in 1991 that made it possible to detect it in blood samples. It is thus a relatively newly identified disease and there are still many aspects of it that are little or poorly understood. There are an estimated 130-170 million people worldwide infected with hepatitis C but the level of infection, known as prevalence, varies widely from country to country. In some countries, such as Egypt it is over 10%; in the US it is believed to be nearly 2% and in northern Europe around 1%. Prevalence in the UK is 1-2.5%. Transmission is by contact with infected blood. http://www.hepctrust.org.uk/hepatitis-c

(d.) CJDs: Creutzfeldt Jakob Disease (CJD) is an invariably fatal human disease belonging to the Transmissible Spongiform Encephalopathies (TSEs). These conditions are caused by a pathological accumulation in the brain of an aberrant form (PrPSc) of a normal cell surface glycoprotein, prion protein (PrP). CJD occurs in familial, sporadic and acquired (variant CJD and iatrogenic) forms. The familial forms of CJD are autosomal dominant traits associated with mutations in the prion protein gene (PRNP). At present, sporadic CJD (sCJD) is the most commonly encountered form of the disease with an incidence of 1 case per million, thus giving approximately 60 new cases per year in the UK. Patients with sCJD are predominantly in their 60s and as such come into contact with ophthalmologists through a range of unrelated ophthalmic conditions or because of visual symptoms caused by their condition. Iatrogenic CJD has been associated most recently with blood transfusion (3 clinical vCJD cases), and historically with human cadaveric growth hormone treatment (>190 cases), dura mater transplantation (>190 cases), contaminated neurosurgical instruments/EEG needles (6 cases) and corneal transplantation. Instruments used in high or medium risk procedures on patients with, or “at increased risk” of, CJD/vCJD can be quarantined and reused exclusively on the same patient, subect to tracking of instruments throughout the decontamination cycle, and ensuring that under no circumstances should quarantined instrument sets be reprocessed for use on other patients unless the diagnosis of CJD or vCJD has been positively excluded. Tissues and materials deemed to be low risk include body fluids such as urine, saliva, sputum, blood, and faeces. Blood from vCJD patients is considered to be low risk except when transfused in large volumes. Source: Department of Health http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm#jumpTo3

2.04 - General Procedures

IPEN trained Placenta Encapsulation Specialists are to operate their service according to instructions given during training and to follow guidelines set in the IPEN Code of Practice as well as updates to the Code of Practice made in the future. It is the Specialists personal responsibility to operate according to these guidelines reducing the risks to both their own health and the health of their clients. IPEN Specialists should review these guidelines on a regular basis, checking for updates to the Code of Practice and to reduce health risks during day to day practice.

2.05 – Food Hygiene Guidelines

Working with Food / Placentas

Before you start working with food:

1. Always wash hands in a designated hand-washing basin separate from the basin/sink used to wash food/placenta. This basin should be on the same ground level as your preparation sink.
2. Take off any watch and/or wrist jewellery.
3. Always wear vinyl gloves at all times when handling and preparing placenta.
4. Wear clean clothing and protective disposable apron.
5. Pull hair back away from face and/or wear a hat or hairnet.
6. Where appropriate protective eyewear.
7. Clean your home and workspaces regularly. Use a regular household disinfectant to wash commonly used kitchen surfaces every day and before beginning food/placenta preparation.

When you are working with placentas (food):

1. No smoking
2. No eating or drinking
3. Avoid touching your face, coughing or sneezing over food
4. Cover cuts with a brightly coloured waterproof dressing

Washing hands effectively:

1. Wet your hands thoroughly under warm running water and squirt liquid soap onto your palm
2. Rub your hands together palm to palm to make a lather
3. Rub the palm of one hand along the back of the other and along the fingers. Repeat with the other hand
4. Put your palms together finger interlocked and rub in between each of the fingers thoroughly
5. Rub around your thumbs on each hand and then rub the fingertips of each hand against your palms
6. Rinse off the soap with clean water and dry your hands thoroughly on a disposable towel. Turn off the tap with the towel and then throw the towel away

When to wash your hands and wear clean gloves:

1. Before handing equipment, utensils and preparing your space for work
2. After going to the toilet
3. After every break
4. After touching a cut or changing a dressing
5. After touching or emptying bins
6. After any cleaning
7. After touching phones, light switches and door handles
8. After changing vinyl gloves during placenta preparation

Raw/Cooked Food guidelines: Avoiding cross-contamination

a) Store placentas in a separate cool box only and not in the home refrigerator of the Specialist
b) Never use reusable cloths to absorb excess blood when preparing raw placentas for raw capsules or when making placenta prints. Use disposable white paper towel only.
c) Cooked food stacked above raw food – Steamed TCM prepared placenta slices must be dehydrated on the top 2 trays of the dehydrator machine, lower tray for umbilical cord.
d) When making both TCM and raw dried capsules from one placenta (or twin placentas), special care and caution taken.
    i) Separate utensils used for each stage 1 processing
    ii) Raw placenta stacked below cooked placenta on dehydrator machine.
    iii) Grind dried raw slices and dried TCM slices in separate clean and sterilised grinder units.

iv) Encapsulate TCM and raw dried powder using separate washed, sterilised and dry capsule machine, bowls and tray.
v) TCM and raw dried capsules stored in separate jars labelled appropriately.

e) Raw placenta dehydrator temperature setting - 55°C for 8-14 hours or until completely dried
f) TCM placenta dehydrator temperature setting - 42°C for 6-10 hours or until completely dried

1.08 – Cleaning and Sterilising Procedures

Measures to control or eliminate contamination of HIV/AIDS, Hep B and Hep C:

(a.) Wear protective clothing (eye goggles, gloves, apron)
(b.) Wash hands regularly using a separate hand washing facility
(c.) Dehydrator trays and kitchen surfaces must be lined with parchment paper to prevent direct contact
(d.) Clean and disinfect all reusable equipment with tested cleansers and sterilisers (Stabimed/Helizyme)

Plastic Equipment

- **Washing:**
  - Using scrubber brush and sponge (discard sponges after use)
  - Anti-bacterial Soap or Helizyme (enzymatic cleaner – for effective removal of organic films, blood, secretions, mucus and other organic contaminants)
  - Wash and scrub thoroughly and rinse in hot water

- **Sterilising:** (disinfect against bacteria, TbB, fungi, viruses (incl. HBV, HIV and HVC) Protective clothing and eye goggles must be worn when using these products
  - STABIMED: (water L x 0.5%) / hours soaking = ml of Stabimed

Stabimed Dilution Chart	80L water	60L water	40L water	20L water
6 hours	67ml	50ml	33ml	16ml
4 hours	100ml	75ml	50ml	25ml
2 hours	200ml	150ml	100ml	50ml
1 hour	400ml	300ml	200ml	100ml

  - BLEACH: 1 part thin bleach to 10 parts water

- **Rinsing:** Thoroughly rinse all equipment in hot water (use shower head or similar)

Stainless Steel equipment (steamer pot, knives and fork)

- Scrub spotlessly clean using steel wool pad and antibacterial soap or Helizyme
- Sterilise in home oven at 70°C for 1 hour – allow to cool before handling

(e.) Cleaning of Surfaces
  - Surfaces within the operation kitchen must be cleaned using disinfectant spray and sponge as well as sterilised using **Clinell Sanitising Wipes** or undiluted bleach. (sinks, taps, kitchen worktops, tiles, stove worktop, cooler bag, ice packs)

(f.) Do not collect or prepare placentas from members of the public who have or suspected to have tested positive for HIV, Hep B or Hep C
(g.) Ensure cleaning and preparation waste products and unused placental tissue, ei. Smoothie blender, gloves, paper towels, bags and other clothes or sponges use are thrown away in appropriate hospital hazard waste bins or washed in bleach, double bagged and disposed of in general waste.

1.09 – Waste

(a.) Spillages:
Standard disinfection for spillages (eg. 10,000ppm chlorine releasing agent, undiluted bleach) should be used to decontaminate the surface after the spillage has been removed or Clinell Sanitising Wipes used to disinfect the clean surface after a spill.

(b.) Disposal of Waste:
Because of the very small amount of blood and/or tissue disposed of when performing a placenta encapsulation there is no need to dispose for incineration. Blood and tissue waste and/or cleaning tools such as towels, cloths, mop heads and kitchen towel should all be placed into a sealed plastic bag, covered in 50-100ml of undiluted bleach and disposed of in the general household waste bin.

(c.) Disposal of excess blood:
Excess blood from placenta storage containers should be disposed of down the toilet followed by 50ml of undiluted thick bleach.

1.10 – IPEN Specialist Rules

(a.) Adhering to HPA (Human Tissue Act 2004) Specialists must have written consent to store and handle the placenta from every Client
(b.) Clients must fill in the IPEN Booking form and sign the attached Terms and Conditions of Service
(c.) Under no circumstances should a Specialist handle a placenta that may be infected with any of the above blood borne viruses
(d.) All equipment must be cleaned thoroughly and sterilised in between each client and equipment should be dried and stored in a large plastic lidded bin between use
(e.) Specialists should ensure they follow the guidelines given in the Code of Practice without hesitation and ensure up to date Risk Assessments are read through and Action is taken to minimise or eliminate risk
(f.) Specialists must report to their local HPU (Health Protection Unit) any circumstance where contamination may have occurred for the safety of both the Client and the Specialist
(g.) It is the Specialists duty to carry out safe and hygienic practices when dealing with the placenta and during the making of placenta capsules for consumption
(h.) The Specialist must complete the Client Report Form after every Client encapsulation.

2.09 - Staff Health

All accidents of contamination where a Client or Specialist may have been exposed to a blood borne virus must be reported to the Specialists local HPA (Health Protection Agency).
Specialists must ensure the Code of Practice is followed to minimise the risks of these incidences to occur.

2.10 - Testing and Maintenance

Specialists should test their electrical equipment before using on the placenta of each client.
(a.) Dehydrator switched on ensure warm air is flowing normally
(b.) Grinders turned on and tested to ensure blade is turning normal and locking mechanism is working properly

2.11 - Emergency Procedures

In cases where Specialists are unable to complete an encapsulation IPEN must be notified immediately. IPEN will aim to make alternative arrangements that suit the Client.
Health Protection Agency Emergency Contact Numbers:
(a.) **Chemicals:** 01235 824852
(b.) **Infectious Disease:** 020 8200 4400 or 020 8200 6868
All incidences occurring during the making of placenta capsules by an IPEN Specialist should be reported to IPEN as soon as possible after contacting the appropriate emergency contact number above.